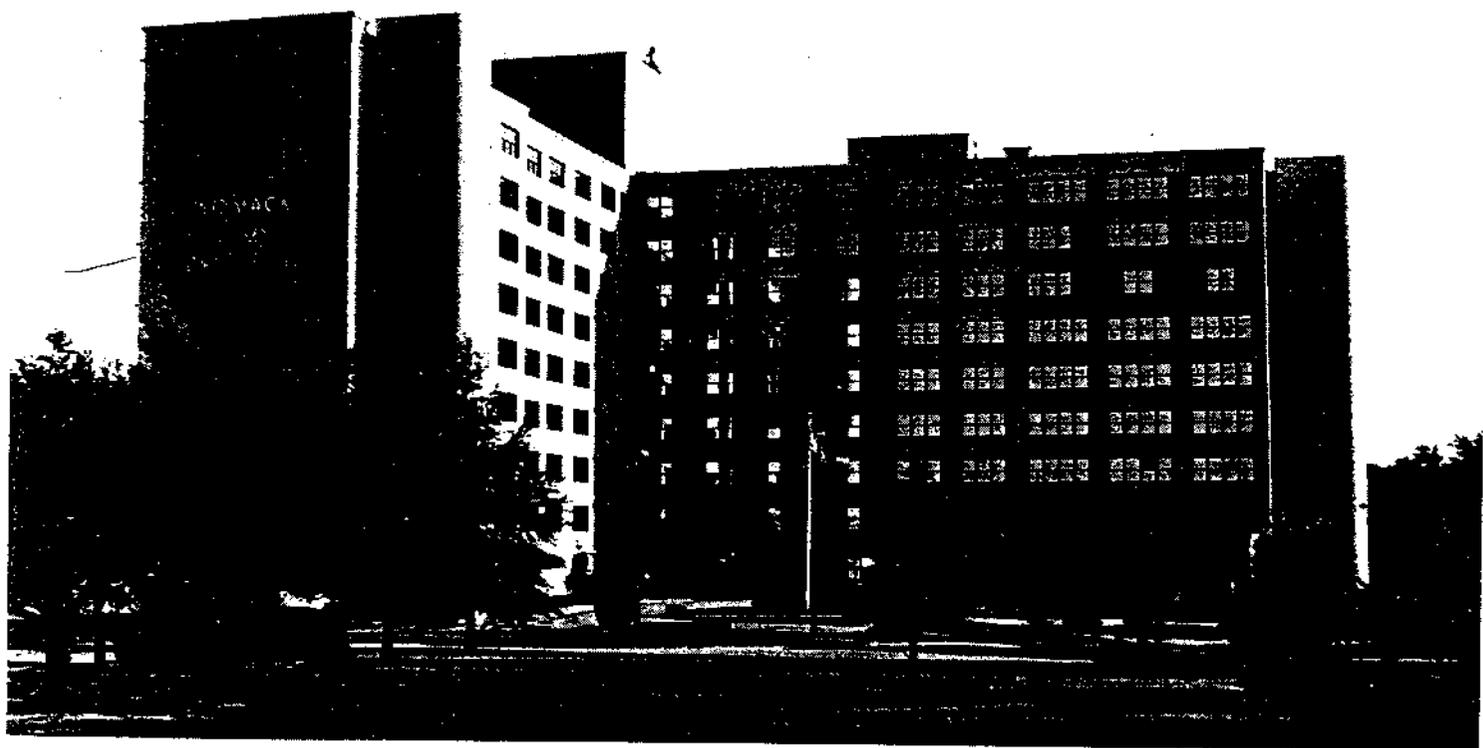


ANNUAL PROGRESS REPORT FY 93



**CLINICAL INVESTIGATION SERVICE
WOMACK ARMY MEDICAL CENTER
FORT BRAGG, NC 28307-5000**

CLINICAL INVESTIGATION PROGRAM

CLINICAL INVESTIGATION

PROGRAM REPORT

1 October 1993

CONTROL SYMBOL: RCS MED-300 (R1)

Department of Clinical Investigation
Womack Army Medical Center
Fort Bragg, North Carolina 28307-5000

DESTROY THIS REPORT WHEN NO LONGER NEEDED. DO NOT RETURN IT TO THE ORIGINATOR.

The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.

Approved for Public Release: Distribution Unlimited.

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Foreward

Clinical Investigation was approved as a modified mission for Womack Army Community Hospital in May, 1990. Due to the deployments in support of Operation Desert Shield/Desert Storm, our first efforts at the research review and approval process did not take place until the Fall of 1991. Significantly, Womack was designated a medical center that same autumn. This second annual progress report records our steps as we grow into the role of a medical center.

More fertile ground than Fort Bragg for patient-oriented, clinically-based scholarly activity could not be imagined. With approximately 50,000 active duty members and over 200,000 beneficiaries in our catchment, the clinical material is indeed ample. Certainly, this population is recognized by the Walter Reed Army Institute of Research, and the U.S. Army Medical Research Institute for Infectious Disease, who (among others) periodically conduct studies at Fort Bragg. Sadly, the involvement of the Womack clinicians in research is low simply because the patient care burden is high. My hope is that the potential for Fort Bragg for patient-based research of military medical significance will be fully recognized in the years ahead. I also hope that, as scarce personnel resources are re-aligned in the Army medical community, these individuals will be appropriately committed toward the realization of this immense potential.

I remain indebted to the leadership of Womack Army Medical Center for their commitment to an entry-level clinical investigation program. It would not have occurred without the support of the Commander, Colonel Harold Timboe, and the DCCS, Colonel Stephen Jones. LTC(P) Joe FitzHarris, as Chief of the Department of Family Practice, enabled a physician and secretary to be committed to the Clinical Investigation Service and continues to strongly support scholarly endeavor.



VICTOR G. McGLAUGHLIN, M.D.
Major, Medical Corps
Director, Clinical Investigation
Service

Unit Summary

A. Objective

To implement and manage the Clinical Investigation Service at Womack Army Medical Center (WAMC), Fort Bragg, North Carolina by promoting, supporting, coordinating, and providing the atmosphere of inquiry necessary to stimulate clinical medical investigation.

B. Technical Approach

The Clinical Investigation Service at WAMC is conducted by careful monitoring of all approved protocols to assure strict compliance with the following applicable regulations:

AR 40-7	Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances
AR 40-38	Clinical Investigation Program
AR 70-25	Research and Development Use of Volunteers as Subjects of Research
AR 40-37	Licensing and Control of Radioactive Materials for Medical Purposes
HSC 40-23	Management of Clinical Investigation Protocols and Reports

C. Staffing

Description	Rank	MOS	Branch	Name
Director	O4	61H	MC	McGlaughlin, V
Protocol Coord	O4	0679	GS	Collazo, K
FACT Coord	-	-	-	Wolf, T

Institutional Review Committee - Clinical Investigation Committee

Stephen Jones, COL, MC	Chairman DCCS
Victor McGlaughlin, MAJ, MC	Co-Chairman Director, Clinical Investigation
William Eggebrotten, LTC, MC	Chief Department of Surgery
Nathan Erteschik, LTC, MC	Chief Department of Medicine
Mark Silechnik, LTC, MC	Chief Department of Obstetrics/Gynecology
Bonnie MacGhee, LTC, AN	Representing Chief Department of Nursing
Sharon Cooper, COL, MC	Chief Department of Pediatrics
George Suchko, LTC, DC	Chief WAMC Dental Activities
Kelly McKee, LTC, MC	Chief Preventive Medicine Service
Robert Sikora, LTC, MS	Chief Pharmacy Service
Joseph FitzHarris, LTC, MC	Chief Department of Family Medicine
Gary Dier, MAJ, MC	Chief Department of Radiology
Ronald Dutton, LTC, VC	DC for Veterinary Services
Thomas Jewell, MAJ, MS	Chief Department of Pathology
Thomas Dudley, MAJ, CH	Chief Ministry & Pastoral Care
Earl Parson, MAJ, MC	Representing Chief Department of Psychiatry/Neurology
Darren Fong, 1LT, MS	Representing Chief Social Work Service
Donald Spear, CSM	Lay/Non-affiliated Representative 307th Medical Battalion

Human Use Committee

Stephen Jones, COL, MC	Chairman DCCS
Victor McGlaughlin, MAJ, MC	Co-Chairman Director, Clinical Investigation
Bonnie MacGhee, LTC, AN	Representing Chief Department of Nursing
Thomas Dudley, MAJ, CH	Chaplain Chief, Ministry & Pastoral Care
Earl Parson, MAJ, MC	Representing Chief Department of Psychiatry/Neurology
Corrine Bridges, LTC, JA	Chief, Claims Office Staff Judge Advocate
Donald Spear, CMS	Lay/Non-affiliated Rep - 307th Med

RESEARCH AWARD RECIPIENTS

Recipient of

The Uniformed Services Academy of Family Physicians
Resident Research Award

was

Captain Craig N. Boss

for his paper

"Mucoepidermoid Carcinoma"

The paper was presented in Corpus Christi, Texas winning second place.

Recipient of

The Uniformed Services Academy of Family Physicians
Staff Research Award

was

Lieutenant Colonel Gary Goforth, MC

for his paper

"Rural and International Medicine: Innovative
Curriculum in a Family Practice Residency Program"

The paper was presented in Corpus Christi, Texas winning second place.

Recipient of

The National Congress of Family Practice Residents
STFM Research Forum

was

Captain Michael Schooff

for his paper

"Influences in Medical Specialty Selection of 1991
Graduates of the USUHS"

The paper was presented in Kansas City, Missouri winning first place.

Recipient of

The Southern Medical Association
Resident Research Award

was

Captain Bryan Smith

for his paper

"Acute Appendicitis in the Puerperium: A Case Report
and Literature Review"

The paper was presented in New Orleans, Louisiana winning second
place.

Recipient of

The Southern Medical Association
Resident Research Award

was

Captain Michael Schooff

for his paper

"Neurosarcoidosis: An unusual etiology
of headache"

The paper was presented in New Orleans, Louisiana winning first
place.

Clinical Investigation Service

Year initiated and Protocol #	Protocol Title	Page
1992 92001	The Nedocromil Sodium Inhalation Aerosol Clinical Experience Study: An Evaluation of Nedocromil Sodium Inhalation Aerosol in Symptomatic Patients with mild to moderate asthma. (T)	5
1992 92002	Long-Acting Converting Enzyme inhibition use in elderly, hypertensive patients: A nationwide survey. (C)	6
1992 92003	A comparison of the efficacy, safety and tolerance of ceftibuten 300mg given BID and augmentin 500mg given TID in the treatment of community acquired Pneumonia. (T)	7
1992 92004	A comparison of the efficacy, safety and tolerance of ceftibuten 400mg in the fed and fasted state and augmentin amoxicillin/clavulante 1.5gm in the fed state in the treatment of acute exacerbations of chronic Bronchitis. (T)	8
1992 92005	The influence of work on the outcome of pregnancy in military and non-military nulliparous women. (C)	9
1992 92006	Tick-borne disease surveillance in febrile hospitalized patients. (C)	10
1992 92007	Fluoride concentrations in Human Bone. (C)	11

Code: C = complete, T = terminated, O = ongoing

Clinical Investigation Service

Year initiated and Protocol #	Protocol Title	Page
1992 92008	Fort Bragg Tick-borne disease study: Womack Family Practice Clinic (non- active duty outpatients.) (C)	12
1992 92009	A comparison of functional recovery rates using circumferential, collateral and focal continuous compression following grade II ankle inversion injuries. (C)	13
1992 92010	Ultrasound Guided Percutaneous Needle Core Biopsy. (T)	14
1992 92011	A double blind, placebo controlled parallel group, multicenter study of the use of weekly Azithromycin as Prophylaxis against the development of Mycobacterium Avium Complex disease in HIV infected people. (O)	15
1992 92012	The Prevalence of Degenerative Joint Disease of the spine in Airborne Infantry, non-airborne infantry, and combat service support personnel. (C)	16
1992 92013	Immunization of Military Personnel with Hepatitis A vaccine. (O)	17
1992 92014	Safety and Immunogenicity of a Hepatitis A vaccine. (O)	18
1993 93015	A double blind, placebo controlled study of the efficacy and safety of three doses of CP-0127 and placebo in patients with presumed Sepsis and the Systemic Inflammatory Response Syndrome (SIRS). (O)	19

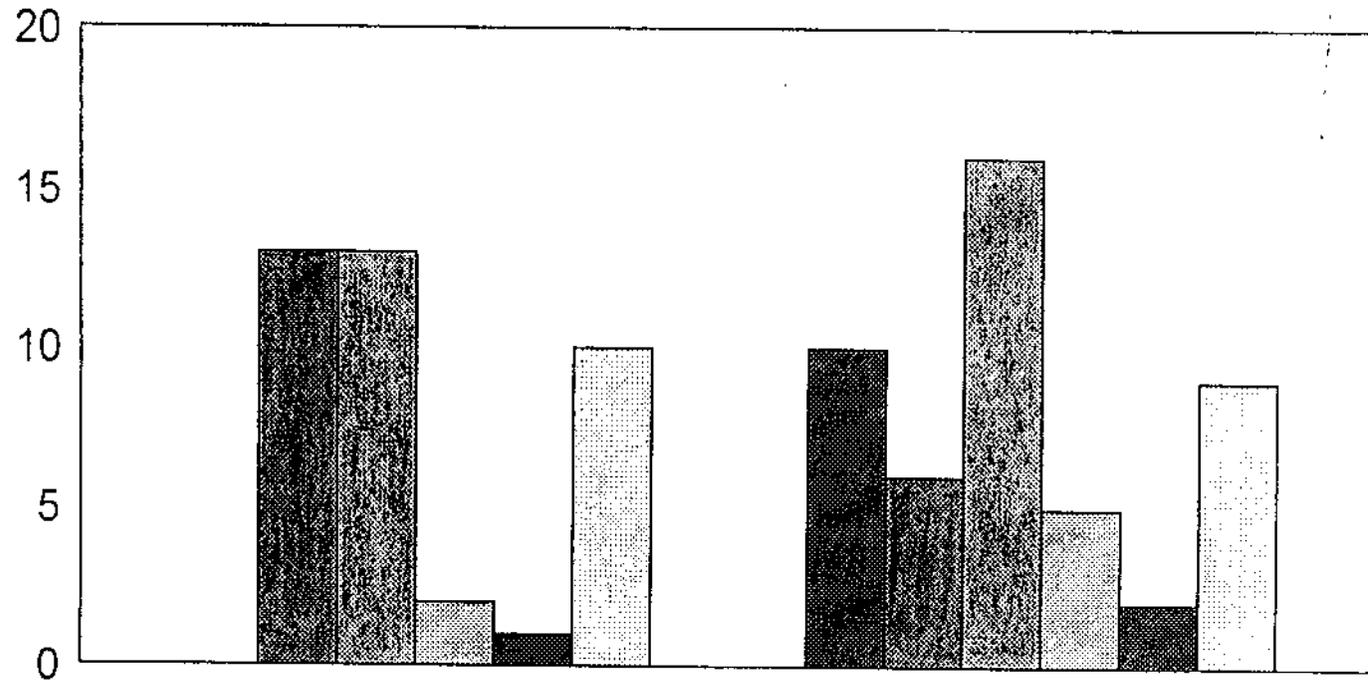
Code: C = complete, T = terminated, O = ongoing

Clinical Investigation Service

Year Initiated. and Protocol #	Protocol Title	Page
1993 93016	The effect of cricoid pressure on intraocular pressure in supine human subjects. (C)	20
1993 93017	Use of sustacal stimulation testing to to differentiate between early onset type I and type II Diabetes Mellitus. (O)	21
1993 93018	Immunization with a highly purified vaccine (FSME-IMMUN inject) against tickborne encephalitis: comparison of an accelerated versus standard schedule. (O)	22
1993 93019	Treatment of Adult Patients with Varicella with short course oral Acyclovir. (O)	23

Code: C = complete, T = terminated, O = ongoing

WAMC Protocol Activity

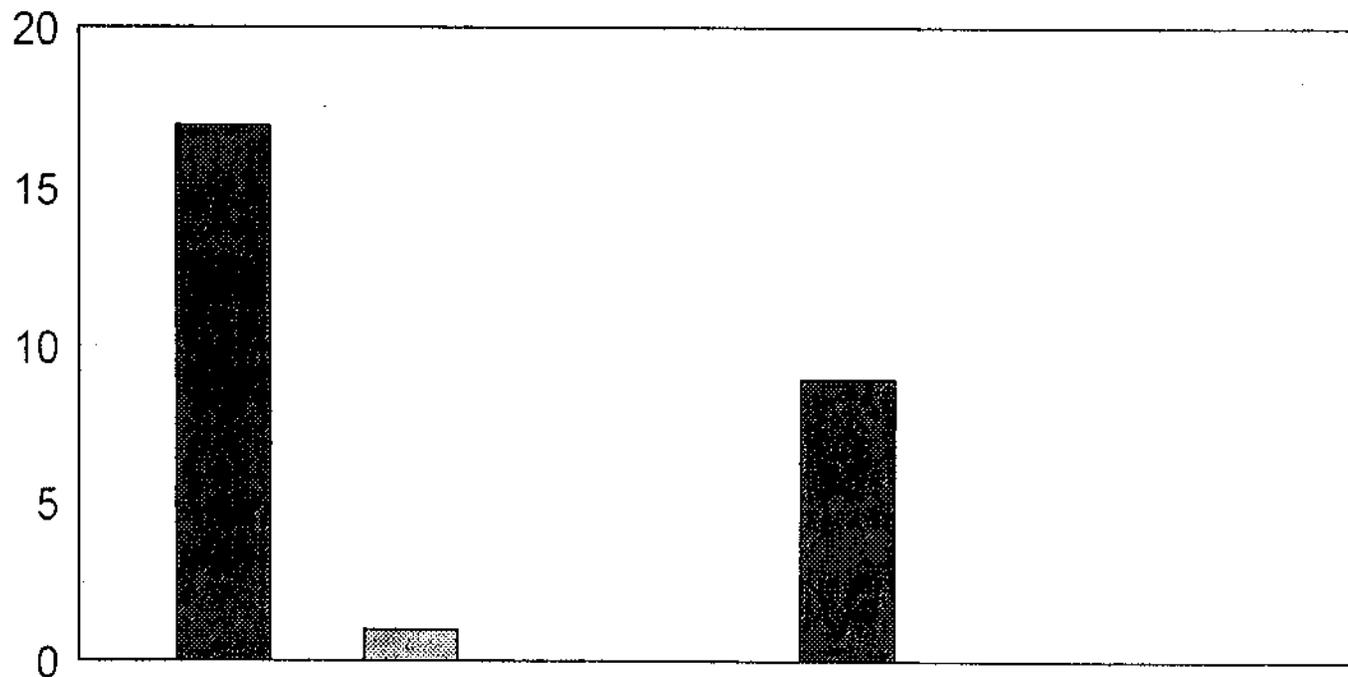


	FY92	FY93
Ongoing FY	0	10
Approved	13	6
Total Active	13	16
Complete -	2	5
Terminated	1	2
Ongoing FY	10	9

FY93 Active Investigations by Subject

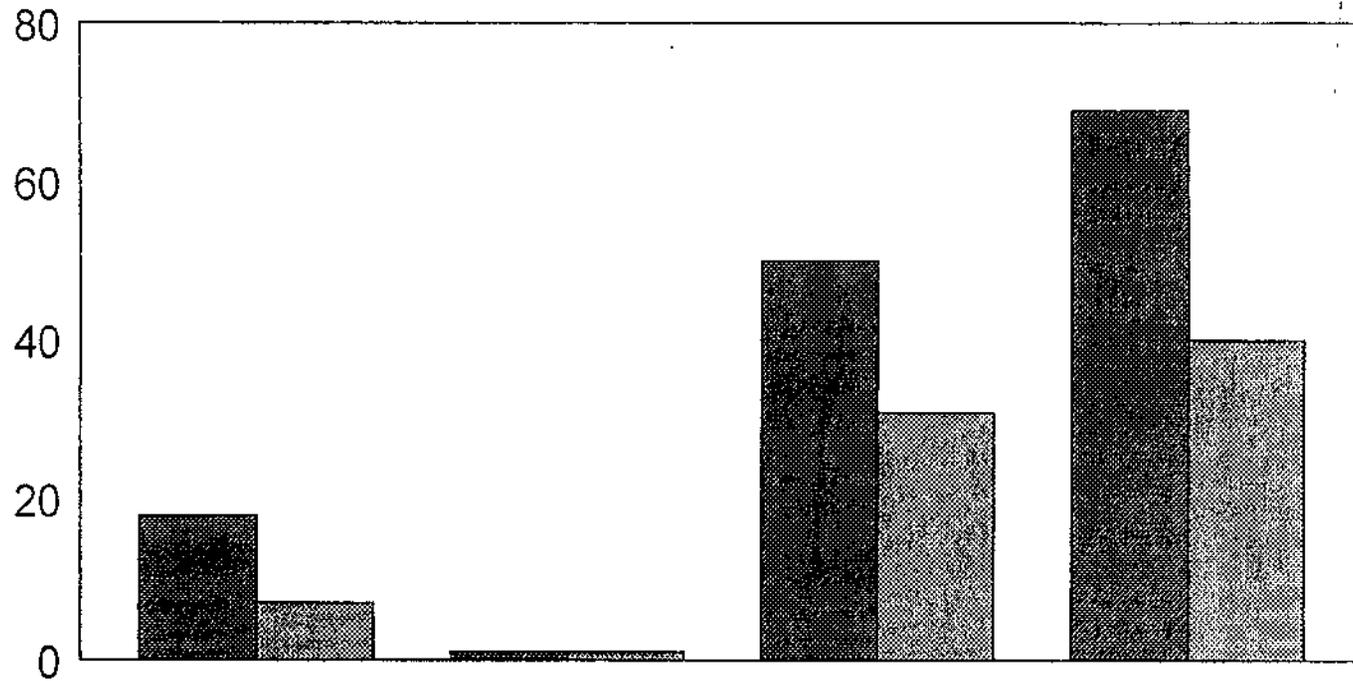
	Terminated	Completed	Active
IND	0	0	4
Device	0	1	0
Expedited	0	3	1
Greater Risk	1	1	4
Animal	0	0	0
Laboratory	0	0	0
Total	1	5	9

FY93 Active Investigations by AMEDD Officer Corps



	Number	Active Studies
MC	17	9
MS	0	0
Dental	1	0
Nursing	0	0
Veterinary	0	0

WAMC Publications & Presentations



	Articles (Pub)	Abstracts	Presentations	Total
FY92	18	1	50	69
FY93	7	1	31	40

FY 93 Publications & Presentations

Pharmacy Service

Bjornson D., Hiner W., Potyk R., Nelson B., Lombardo F., Morton T., Larson L., Martin B., Sikora R. and Cammarata F. Effect of Pharmacists on Health Care Outcomes in Hospitalized Patients. American Journal of Hospital Pharmacy, Vol 50, pp 1875-1884. Sept 93. (P)

Department of Psychiatry/Neurology

Russell, ML., Spector JS., Primacy and Recency Effects in the Detection of Malingering using the WMS-R Logical Memories Subtests. Journal of Clinical and Experimental Neuropsychology, Vol 15(1), pp.109. 1993 (P)

Russell, ML., Spector JS., Primacy and Recency Effects in the Detection of Malingering using the WMS-R Logical Memories Subtests. International Neuropsychological Society, 21st Annual Meeting, 24-27 Feb 93, Galveston, TX. (Pr)

Department of Surgery

Stannard, J., Bucknell, A., Rupture of the Triceps Tendon Associated with Steroid Injections. The American Journal of Sports Medicine, Vol 21(3), pp. 482-485. May 1993. (P)

Stannard, J., James P., Harris, R., Buckness A., Cossi, A. and Ward, J. Pulsatile Plantar Compression as Prophylaxis Against Deep Vein Thrombosis following Total Hip Arthroplasty. American Journal of Bone and Joint Surgery - Sept 93. (P)

Modesto, V., Jones JC., Satava R., Chandra V., Delayed Hemorrhage as a Manifestation of Occult Vascular Injury. Military Medicine. Feb 1993. (P)

Jones JC., Letter for Editor., Reference: Dowling RD., Ferson PF, Landreneau RJ. Thoracoscopic Resection of Pulmonary Metastases. Chest 1992; 102:1450-1454. 1993. (P)

Lenczyk, M., Stern, L. Effect of Environmental Temperature Extremes. Problems in Anesthesia, Lippencott. (P) pending

Kline, M., Guzzi, L., Reynolds, P., Stoltzfus, D., Hagemeister, B. Patterns of Ischemia-Holter Monitoring following Non-Cardiac Surgery in patients with previous PTCA or CABG. Anesthesiology, Vol 77, 3A, A90. (A)

P = Publication, Pr = Presentation, A = Abstract

FY 93 Publications & Presentations

Department of Surgery

Ciresi, S., Upper Extremity Blockade, Charlotte Anesthesia Society, Feb 93, Charlotte, NC. (Pr)

Ciresi, S., History of Military Anesthesia, Medforce 2000: Field Medicine Update, 1993, Fort Bragg, NC. (Pr)

Cassinelli. Drawover Anesthesia: Development and Application, Medforce 2000: Field Medicine Update, 1993, Fort Bragg, NC. (Pr)

Lenczyk, M., Karen S., Muldoon, S., Freese, R. Effects of Ischemia and Reperfusion on the Halothane Contracture Test. American Society of Anesthesiology National Meeting, 1993, New Orleans, LA. Anesthesia Resident Research Award - 3rd Place. (Pr)

Lenczyk, M. Patel R., Hanallah R., McGill W., Desaturation Time in Apneic Children following Pre-Oxygenation: Effect of Age. Society for Ambulatory Anesthesia Annual Meeting, 1993, Scottsdale, AZ. (Pr)

Stannard, J., Harris, R., Intermittent Compression of the Planter Venous Plexus following total Joint Arthroplasty. Society of Military Orthopaedic Surgeons. Nov 30-Dec 4, 1992. Colorado Springs, CO. (Pr)

Harris, R., Stannard J., Intermittent Planter Compression as treatment for swelling after External Fixation. Society of Military Orthopaedic Surgeons, Nov 30-Dec 4, 1992. Colorado Springs, CO. (Pr)

Stannard, J., Harris, R., Intermittent Compression of the Planter Venous Plexus following total Joint Arthroplasty. 60th Annual Meeting of the American Academy of Orthopaedic Surgeons, 18-24 Feb 93, San Francisco, CA. (Pr)

Harris, R., Stannard J., Intermittent Planter Compression as treatment for swelling after External Fixation. 60th Annual Meeting of the American Academy of Orthopaedic Surgeons, 18-24 Feb 93, San Francisco, CA. (Pr)

Stannard, J., Harris R., DVT Prophylaxis following hip fractures: A new therapeutic approach. Orthopaedic Trauma Association, 24-26 Sept 93, New Orleans, LA. (Pr)

P = Publication, Pr = Presentation, A = Abstract

FY 93 Publications & Presentations

Urology Service

Quinones, D. Renal Embolization. Kimbrough Urological Meeting (SGSU), Dec 92, Seattle, WA. (Pr)

Quinones, D. Update on Prostate Cancer, Physicians' Assistants Annual Meeting, Apr 93, Fayetteville, NC. (Pr)

Department of Family Medicine

Griffiths, G. Teen Sexual Activity: Can Family Physicians have an Impact?. USAFP, 21-26 Mar 93. Corpus Christi, TX. (Pr)

Vorwald, F. Smoking Cessation and Family Types in Participants of Smoking Treatment Programs. USAFP, 21-26 Mar 93. Corpus Christi, TX. (Pr)

Boss, C. Mucoepidermoid Carcinoma. USAFP, 21-26 Mar 93. Corpus Christi, TX. (Pr)

Hyatt, A. Bronchopulmonary Aspergillosis presenting as Atypical Pneumonia. USAFP, 21-26 Mar 93. Corpus Christi, TX. (Pr)

Snoddy, R. Medical Consequences of Basic Infantry Training and Predictors of Training Success. USAFP, 21-26 Mar 93, Corpus Christi, TX. (Pr)

Goforth, G. Rural and International Medicine: Innovative Curriculum in a Family Practice Residency Program. USAFP, 21-26 Mar 93, Corpus Christi, TX. 2nd Place Research Award Recipient. (Pr)

Schooff, M. Influences in Medical Specialty Selection of 1991 Graduates of USUHS. National Congress of Family Practice Residents, Aug 93, Kansas City, MO. 1st Place STFM Research Forum. (Pr)

Wolboldt, C. Hyponatremia secondary to Water Intoxication: A case report and literature review. USAFP, 21-26 Mar 93, Corpus Christi, TX. (Pr)

McGlaughlin, V. Introducing new residents to the specialty of Family Practice: A curriculum approach. USAFP, 21-26 Mar 93, Corpus Christi, TX. (Pr)

Lang, W. A computerized information system for Family Practice Residencies. USAFP, 21-26 Mar 93, Corpus Christi, TX. (Pr)

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FY 93 Publications & Presentations

Department of Family Medicine

Schooff, M. Intussusception: An uncommon presentation of a common disease. SMA, 28-31 Oct 93, New Orleans, LA. (Pr)

Keehn, M. Thrombotic Thrombocytopenic Purpura in the Puerperium. SMA, 28-31 Oct 93, New Orleans, LA. (Pr)

Lawrence, W. Nephrolithiasis during Pregnancy: A case report and literature review. SMA, 28-31 Oct 93, New Orleans, LA. (Pr)

Light, D. Do Zung Self-Rating Depression scores vary with duration of Pregnancy? SMA, 28-31 Oct 93, New Orleans, LA. (Pr)

Smith, B. Acute Appendicitis in the Puerperium: A case report and literature review. SMA, 28-31 Oct 93, New Orleans, LA. 2nd Place Resident Research Recipient Award. (Pr)

Thompson, B. Mycobacterial Cellulitis: A case report and literature review. SMA, 28-31 Oct 93, New Orleans, LA. (Pr)

Schooff, M. Neurosarcoidosis: An unusual etiology of headache. SMA, 28-31 Oct 93, New Orleans, LA. 1st Place Resident Research Recipient Award. (Pr)

Preventive Medicine Service

Jenkins, P. Situational Factors in STD Incidence: A neglected area of inquiry. IX International Conference on AIDS, 7-11 Jun 93, Berlin, Germany. (Pr)

P = Publication, Pr = Presentation, A = Abstract

REPORT DATE: 9/15/92

PROTOCOL: #92001

Detail Summary Sheet

TITLE: The Nedocromil Sodium Inhalation Aerosol Clinical Experience Study: An Evaluation of Nedocromil Sodium Inhalation Aerosol in Symptomatic Patients with Mild to Moderate Asthma

KEYWORDS: asthma, asthma treatment

PRINCIPAL INVESTIGATOR: McGlaughlin, Victor, MAJ, MC

DEPARTMENT: Department of Family Medicine

STATUS: Terminated

APPROVAL DATE: Oct 1991

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: To demonstrate improvements in symptoms and global indices of lifestyle in symptomatic patients with mild-moderate asthma after four weeks of treatment with Nedocromil Sodium.

TECHNICAL APPROACH: Multicenter, open label trial. Weekly symptom assessment, pulmonary function testing, and lifestyle indices assessment.

PRIOR AND CURRENT PROGRESS: Womack Army Medical Center was not selected as an investigation site, and no patients were enrolled. Protocol closed - 30 Sept 92.

CONCLUSIONS: None. Study Terminated.

REPORT DATE: 5/22/92

PROTOCOL: # 92002

Detail Summary Sheet

TITLE: Long-Acting Converting Enzyme Inhibition Use in Elderly, Hypertensive Patients: A Nationwide Study.

KEYWORDS: hypertension, elderly, enzyme inhibition use

PRINCIPAL INVESTIGATOR: Swackhammer, Randy, MAJ, MC

DEPARTMENT: Department of Medicine
Internal Medicine

STATUS: Completed

APPROVAL DATE: Oct 1991

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: This trial proposed to examine a national database of elderly, hypertensive patients managed with long-acting converting enzyme inhibitors to assess clinical usage and effects.

TECHNICAL APPROACH: This study was a retrospective, multi-center drug use evaluation of the clinical usage and effects in the elderly (age over 60 years) of ACE inhibitors. Outpatient charts of identified patients were reviewed and case forms completed. Patient, Medication, Safety, and Clinical Response Data was collected.

PRIOR AND CURRENT PROGRESS: This study was completed in May 92 with a total of thirty (30) subjects entered into the study.

CONCLUSIONS: Many of the patients are not controlled despite Combination Therapy. I suspect compliance may be a factor.

REPORT DATE: 1/14/94

PROTOCOL: #92003

Detail Summary Sheet

TITLE: A comparison of the efficacy, safety and tolerance of Ceftibuten 300 mg and Augmentin 500 mg given TID in the treatment of community acquired pneumonia.

KEYWORDS: Pneumonia, Augmentin, Ceftibuten

PRINCIPAL INVESTIGATOR: McGlaughlin, Victor G., MAJ, MC

DEPARTMENT: Department of Family Medicine

STATUS: Terminated, Nov 93

APPROVAL DATE: Jan 1992

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: To compare the efficacy, safety, and tolerance of high dose Ceftibuten (300mg BID) with that of Augmentin (500mg TID) in the treatment of pneumonia in up to thirty adults with culture confirmed pneumonia.

TECHNICAL APPROACH: A randomized, single blind comparison drug study. Data collected via subjective and objective assessment by the physician in the pre-treatment, during treatment and post treatment phase. Data reported via standardized forms. Statistical analyses will be provided by the sponsor and is ongoing.

PRIOR AND CURRENT PROGRESS: As of 19 November 1993 the trial was terminated. Patient enrollment was discontinued 11 Nov 93. A total of +25 potential candidates have been screened with a subsequent enrollment of 11. A total of 5 of the 11 have been rated evaluable by the sponsor.

No serious adverse events reported.

Manpower consisted of the principal investigator and a part time study coordinator provided by the sponsor. Additional technical support is provided by the Womack Army Medical Center Department(s) of Microbiology, Radiology and Outpatient Pharmacy.

CONCLUSIONS: Study enrollment did not reach anticipated levels. Pooled results from the multicenter trial sites are pending.

REPORT DATE: 1/14/94

PROTOCOL: #92004

Detail Summary Sheet

TITLE: A comparison of the efficacy, safety and tolerance of Cefitibuten 400mg in the fed and fasted state and Augmentin 1.5gm in the fed state in the treatment of acute exacerbations of chronic bronchitis.

KEYWORDS: Bronchitis, Augmentin, Cefitibuten

PRINCIPAL INVESTIGATOR: McGlaughlin, Victor G., MAJ, MC

DEPARTMENT: Department of Family Medicine

STATUS: Terminated, 11 Nov 93

APPROVAL DATE: Jan 1992

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: To compare the efficacy, safety, and primarily the GI tolerance of once daily Cefitibuten in both the fed and fasted state with that of Augmentin (500mg TID) in the fed state in the treatment of acute exacerbations of chronic bronchitis.

TECHNICAL APPROACH: A randomized, single blind comparison drug study. Data is collected via subjective and objective assessment by the physician in the pre-treatment, during treatment and post treatment phase. Data is reported via standardized forms. Statistical analyses will be provided by the sponsor.

PRIOR AND CURRENT PROGRESS: As of 19 Nov 93 the trial was terminated due to sufficient participant enrollment. Patient enrollment was discontinued 11 Nov 93. A total of +35 potential candidates have been screened with a subsequent enrollment of 6. Evaluability of the participants is not available at present.

There have been no serious adverse events reported.

Manpower consists of the principal investigator and a part time study coordinator provided by the sponsor. Additional technical support is provided by the Womack Army Medical Center Department(s) of Microbiology, Radiology and Outpatient Pharmacy.

CONCLUSIONS: Study enrollment did not reach anticipated levels. Pooled results from the multicenter trial sites are pending.

REPORT DATE: 10/2/92

PROTOCOL: #92005

Detail Summary Sheet

TITLE: The influence of work on the outcome of pregnancy in military and non-military nulliparous women

KEYWORDS: Pregnancy outcome, work, pregnancy complications

PRINCIPAL INVESTIGATOR: McGlaughlin, Victor G., MAJ, MC

DEPARTMENT: Department of Family Medicine

STATUS: Completed

APPROVAL DATE: Jan 1992

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: To determine (1) if pregnant soldiers have different work and experiences than pregnant civilian workers, (2) if soldiers have a higher rate of complicated pregnancy than civilian workers.

TECHNICAL APPROACH: A prospective cohort study. Each woman consenting to participate completed a questionnaire at 28 weeks gestation, seeking information about work activity and exposures, sources of stress and support at home and in the work place, wellness behaviors and demographics. The responses of pregnant

REPORT DATE: 1/12/94

PROTOCOL: #92006

Detail Summary Sheet

TITLE: Tick-Borne Disease Surveillance in febrile, hospitalized patients

KEYWORDS: tick-borne disease, Lyme disease, Rocky Mountain Spotted Fever

PRINCIPAL INVESTIGATOR: McGlaughlin, Victor G., MAJ, MC

DEPARTMENT: Department of Family Medicine

STATUS: Complete

APPROVAL DATE: Feb 1992

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: A prospective study to determine the relative frequencies of several common tick-borne diseases such as Lyme disease, Ehrlichiosis, Q fever, and Rocky Mountain Spotted Fever in the patients admitted to Womack Army Medical Center.

TECHNICAL APPROACH: The study population consists of all consenting patients, 18 years and older, admitted to Womack. Patients will be enrolled if they have a history of tick exposure within the preceding two weeks. PCR, CBC and liver function tests will be performed. A convalescent titer will be determined from all participating patients 21-28 days after the acute titer is drawn.

PRIOR AND CURRENT PROGRESS: A total of 22 patients have been included into the inpatient study. LFT's and CBC's have been followed every 3 days while in-house. Acute titers have been obtained at that time as well. Convalescent titers have been extremely difficult to obtain and when obtained are often later than four weeks.

CONCLUSIONS: A small number of inpatients had evidence of tickborne disease, but are insufficient to generalize results to the Fort Bragg population.

REPORT DATE: 12/3/93

PROTOCOL: #92007

Detail Summary Sheet

TITLE: Fluoride Concentrations in Human Bone

KEYWORDS: fluoride, bone fluoride concentrations

PRINCIPAL INVESTIGATOR: Davis, Randy MAJ, DC

DEPARTMENT: WAMC Dental Activity

STATUS: Completed

APPROVAL DATE: March 1992

STUDY OBJECTIVE: To determine current bone fluoride concentrations of subjects with a known history of systemic fluoride exposure.

TECHNICAL APPROACH: Bone samples were obtained through cooperation of the Operating Room staff and Orthopedic Surgery. Surgical procedures were identified in which it was anticipated that bone would be removed from patients and discarded. No additional bone was removed for this study. Prior to surgery, the patients were interviewed, a summary of medical history recorded and the best possible fluoride exposure history obtained. Bone specimens from the Operating Room at Womack are assayed at UNC Chapel Hill for bone fluoride concentration.

PRIOR AND CURRENT PROGRESS: 13 samples were collected and all had normal fluoride concentrations. The principal investigator was unable, however, to correlate these bone levels with the water supply fluoride level at the subject's home of record (no response from the various utility departments). The rough draft of the research project has been submitted. An ongoing effort to secure this data is being made.

CONCLUSIONS: None.

REPORT DATE: 10/5/93

PROTOCOL: #92008

Detail Summary Sheet

TITLE: Fort Bragg Tick-Borne Disease Study: Womack Family
Practice Clinic (Non-Active Duty Outpatients)

KEYWORDS: Tick-borne disease, Ehrlichiosis, Lyme disease

PRINCIPAL INVESTIGATOR: Goforth, Gary, LTC, MC

DEPARTMENT: Department of Family Medicine

STATUS: Complete

APPROVAL DATE: March 1992

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: To determine the relative frequency of several common tick-borne diseases such as Lyme disease, Ehrlichiosis, Q fever, and Rocky Mountain Spotted Fever (RMSF) in a non-active duty military population.

TECHNICAL APPROACH: A prospective study utilizing serological and questionnaire data. Manpower consists of the Principal Investigator, Associate Investigators, WAMC laboratory personnel and shipping technician, and Family Practice Clinic Nurses.

PRIOR AND CURRENT PROGRESS: There have been 25 subjects enrolled from 10 Mar 92 - 30 Sept 92.

No serious adverse events noted.

All acute serologic specimens have been collected for the study. 5 convalescent specimens and questionnaires have been received and forwarded to the CDC. The study investigators have completed multiple follow-up attempts to acquire the remainder of the convalescent sera and questionnaires including phone calls and letters to the study subjects. Final results are based on both acute and convalescent sera results.

CONCLUSIONS: None.

REPORT DATE: 11/6/93

PROTOCOL: #92009

Detail Summary Sheet

TITLE: A comparison of functional recovery rates using circumferential, collateral and focal continuous compression following grade II ankle inversion injuries

KEYWORDS: ankle sprain, compression, functional tests

PRINCIPAL INVESTIGATOR: O'Keefe, Ellen, CPT, SP

DEPARTMENT: Department of Surgery
Physical Therapy Section
Department of Orthopedics

STATUS: Complete

APPROVAL DATE: March 1992

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: To compare the rates of functional recovery using different modes of continuous compression following grade II ankle inversion injuries in a healthy male active duty military population.

TECHNICAL APPROACH: This study will examine 300 male active duty personnel with a diagnosis of acute grade II ankle inversion injury by clinical examination. After informed consent, the patient will be randomly assigned to one of three continuous compression groups: circumferential, collateral or focal. Each of the patients will receive standard physical therapy treatment on an outpatient basis. The rate of functional recovery will be measured through the use of an eleven level post-sprain function scale. Clinical measurements will also be used to assess progress in the areas of range of motion, swelling, subjective pain, strength and proprioception.

PRIOR AND CURRENT PROGRESS: As of the last reporting, 65 patients had been screened for enrollment with a subsequent participation of 38.

No serious adverse events were noted.

Manpower consists of the principal investigator, the associate investigator, a physical therapy technician and an orthopedic technician. WAMC Department of Radiology provides technical support.

CONCLUSION: None. The principal investigator has been temporarily assigned overseas and was not available to respond to the conclusions of this study.

REPORT DATE: 5/12/93

PROTOCOL: #92010

Detail Summary Sheet

TITLE: Ultrasound guided percutaneous needle core biopsy

KEYWORDS: breast mass, breast cancer, breast biopsy

PRINCIPAL INVESTIGATOR: Burke, Brian, CPT, MC

DEPARTMENT: Department of Radiology

STATUS: Terminated

APPROVAL DATE: March 1992

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: This study seeks to evaluate radiologic aspects of core biopsy and to discern if the method can effectively diagnose breast carcinoma pre-operatively.

TECHNICAL APPROACH: Prospective, blinded study of fifty (50) patients who would undergo ultrasound-guided needle core breast biopsy, followed by surgical excisional biopsy, and have independent pathologic correlation of their biopsy results. Subjects are those women with suspicious lesions who would undergo surgical biopsy anyway.

PRIOR AND CURRENT PROGRESS: Study was terminated due to ETS of the Principal Investigator. No study subjects were enrolled.

CONCLUSIONS: None.

REPORT DATE: 4/9/93

PROTOCOL: #92011

Detail Summary Sheet

TITLE: A double-blind, placebo controlled, parallel group, multicenter study of the use of weekly Azithromycin against the development of Mycobacterium Avium Complex Disease in HIV infected people

KEYWORDS: HIV, Mycobacterium Avium Complex, Azithromycin

PRINCIPAL INVESTIGATOR: Kortepeter, Mark, CPT, MC

DEPARTMENT: Department of Medicine
Preventive Medicine
Internal Medicine

STATUS: Ongoing

APPROVAL DATE: May 1992

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: To study the efficacy of Azithromycin in prophylaxis of MAC infection in patients with HIV infection and low CD4 counts.

TECHNICAL APPROACH: This study will enroll all patients with CD4 counts <100/ul who have negative MAC cultures. Screening and baseline evaluations will include a full medical history and physical exam. Blood tests, stool cultures, CXR, and baseline audiometry will be performed. Patients will then be randomized in double-blind fashion to receive Azithromycin 1200mg or placebo as a single dose once a week. Patients will be evaluated clinically once a month and at three months lab and MAC culture will be obtained.

PRIOR AND CURRENT PROGRESS: There are 3 patients enrolled in the study. All three are on medication (placebo or Azithromycin).

No adverse effects of the medication has been noted.

CONCLUSIONS: None. Active recruitment of more patients continues.

REPORT DATE: 8/9/93

PROTOCOL: #92012

Detail Summary Sheet

TITLE: The Prevalence of Degenerative Joint Disease of the Spine
in Airborne Infantry, Non-Airborne Infantry, and
Non-Airborne Combat Service Support Personnel

KEYWORDS: degenerative joint disease, spine, chronic back injury

PRINCIPAL INVESTIGATOR: Craig, Stephen, MAJ, MC

DEPARTMENT: Preventive Medicine
WRAIR

STATUS: Completed

APPROVAL DATE: Feb 1992

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: To determine the prevalence of chronic back injury and degenerative joint disease in the study population.

TECHNICAL APPROACH: This cross-sectional study was conducted in two parts: Part I consisted of a questionnaire and medical records review and Part II consisted of 3 lateral radiographs of the spine. All investigative personnel were from WRAIR and WRAMC. Radiology assets from Womack and BACH, Ft Campbell, KY. were utilized. Troops from the 82nd, 101st, and 18th COSCOM comprised the study population.

PRIOR AND CURRENT PROGRESS: Part I was completed, analyzed and formally presented at the end of the year Residency Advirosy Committee at WRAIR in June 1992. Part II is still currently being analyzed.

CONCLUSIONS: Blacks are less likely to have chronic back pain than whites whether they jump or not. Only night jumping increased the likelihood that a troop would have chronic back pain. Marching or running with a ruck did not increase the odds that a soldier would have chronic back pain.

Part II which consisted of the 3 lateral radiographs of the spine is currently being analyzed. No conclusions as of this report.

REPORT DATE: 10/10/93

PROTOCOL: #92013

Detail Summary Sheet

TITLE: Immunization of Military Personnel with Hepatitis A Vaccine

KEYWORDS: Hepatitis A, immunization

PRINCIPAL INVESTIGATOR: Pittman, Phillip, LTC, MC

DEPARTMENT: USAMRIID Medicine
WRAIR

STATUS: Ongoing

APPROVAL DATE: Sept 1992

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: To make the hepatitis A vaccine available to DOD beneficiaries who may be at risk of contracting hepatitis A as a result of training in or deployment to areas where hepatitis A is endemic and to establish the immunogenicity and reactogenicity of this vaccine when it is given as a double dose compared with two single doses administered one month apart.

TECHNICAL APPROACH: The vaccine will be made available in single-blind fashion to members of the Joint Special Operations Command, according to one of two regiments: approximately half of the individuals will receive a double vaccine dose on day 0, and a saline placebo on day 30; the remainder will receive a single vaccine dose in one arm and saline placebo in the other on day 0, and a single vaccine dose on day 30. Both groups will be boosted at one year with vaccine to anchor the antibody response. Blood samples for serologic analysis will be obtained prior to the first dose (day 0), prior to the booster dose (1 year), and at the conclusion of the project (2 years).

No use of WAMC facilities is anticipated. All clinical work will be conducted within the confines of the JSOC.

PRIOR AND CURRENT PROGRESS: This hepatitis A vaccine at present is an investigational new drug in the U.S. A New Drug Application has been submitted by the manufacturer to the FDA for this vaccine. This submission is based upon results of studies in many thousands of human volunteers.

CONCLUSIONS: Boosters due April-May 1994. No adverse results to date. Study ongoing.

REPORT DATE: 2/18/94

PROTOCOL #92014

Detail Summary Sheet

TITLE: Safety and Immunogenicity of a Hepatitis A vaccine

KEYWORDS: Hepatitis A, immunization, vaccine

PRINCIPAL INVESTIGATOR: Kuschner, Robert, MAJ, MC

DEPARTMENT: WRAIR
Preventive Medicine, Ft Bragg

STATUS: Ongoing

APPROVAL DATE: February 1993

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: Prospective, open label, randomized field study and the objective is to determine if a single high potency dose 1440 EL.U of the hepatitis A vaccine (HM175) will confer a higher seroconversion rate compared to a single dose of the standard potency vaccine 720 EL.U at day 14 following vaccination (comparing groups 1 or 2, vs 3 or 4.)

TECHNICAL APPROACH: This study will compare a standard procedure of administering the vaccine in which Group I will receive one dose at time zero, one dose at time 30 days and one dose at one year; and Group II will receive the first two doses of vaccine simultaneously at time zero and a booster dose at one year. The study will be single blind in which a saline placebo will be administered on day zero to each soldier assigned to Group I and on day 30 to each soldier assigned to group II. All participants will complete a "side effects" questionnaire. Blood samples for serologic analysis will be obtained prior to the first dose (day 0), prior to the booster dose (1 year), and at the conclusion of the project (2 years). 140 volunteers per group (560 total) will be enrolled to meet the final objective of 100 per group at the end of the initial 6 months. Volunteers will be recruited from the US Army Special Operations Command.

PRIOR AND CURRENT PROGRESS: First dose given. Fo final results at this time.

CONCLUSIONS: None. Study ongoing.

REPORT DATE: 1/12/94

PROTOCOL: #93015

Detail Summary Sheet

TITLE: Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Three Doses of CP-0127 and Placebo in Patients with Presumed Sepsis and the Systemic Inflammatory Response Syndrome (SIRS).

KEYWORDS: Sepsis, SIRS, CP-0127

PRINCIPAL INVESTIGATOR: Meyer, James I, MAJ, MC

DEPARTMENT: Internal Medicine

STATUS: Ongoing

APPROVAL DATE: 19 March 1993

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: To assess the safety, efficacy and dose response characteristics of a 72-hour infusion of three doses of CP-0127 or placebo in the treatment of patients with presumed sepsis and SIRS.

TECHNICAL APPROACH: A double-blind, placebo-controlled prospective, randomized and parallel dose ranging study. This study totaling 500 patients will be conducted in 20-40 investigational sites. Patients will be doses for three days with a continuous IV infusion and then followed for a 28 day period. Subjective and objective data will be collected and reported for analyses.

PRIOR AND CURRENT PROGRESS: Progress of the clinical trial includes: organization of the research team, orientation to the protocol, participant awareness and recruitment.

To date, 14 potential patients have been screened in the MICU and 26 pre-surgical patients have screened. No patients have been enrolled to date.

CONCLUSIONS: The majority of these patients at the time they meet enrollment criteria are unable to give informed consent. Consent by proxy is prohibited. Attempts are made to pre-consent patients, the majority of which are unwilling to participate or do not subsequently meet criteria.

REPORT DATE: 2/26/94

PROTOCOL: # 93016

Detail Summary Sheet

TITLE: The effect of cricoid pressure on intraocular pressure in supine human subjects.

KEYWORDS: cricoid pressure, intraocular pressure

PRINCIPAL INVESTIGATOR: Belyea, David, MAJ, MC

DEPARTMENT: Ophthalmology

STATUS: Complete

APPROVAL DATE: March 1993

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: A pilot study to investigate the effect of Cricoid pressure on intraocular pressure in supine human subjects using a small volunteer sample. Subjects will be thirty adult volunteers with no history of increased intraocular pressure, cardiovascular disease or breathing difficulty.

TECHNICAL APPROACH: Subjects will be placed in the supine position and the cornea of one eye will be anesthetized using a topical lidocaine solution. A tonometer, supplied by the Department of Ophthalmology, will be used to record ocular pressure with and without manually applied cricoid pressure. The procedure should be complete within ten minutes.

PRIOR AND CURRENT PROGRESS: Study completed June 1993. Attempt to contact investigators unsuccessful (all have PCS'd or ETS'd).

CONCLUSIONS: Unknown.

REPORT DATE: 2/18/94

PROTOCOL: #93017

Detail Summary Sheet

TITLE: Use of sustacal stimulation testing to differentiate between early onset type I and type II diabetes mellitus.

KEYWORDS: Diabetes Mellitus, sustacal stimulation testing

PRINCIPAL INVESTIGATOR: Humphrey, Michael, MAJ, MC

DEPARTMENT: Department of Medicine
Internal Medicine

STATUS: Ongoing

APPROVAL DATE: March 1993

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: To differentiate between Type I and Type II diabetes in younger patients by measuring insulin and C-Peptide response after a complex caloric meal. In new onset diabetics it is often difficult to characterize them as either type I or type II.

TECHNICAL APPROACH: After an overnight fast, patients will present to the medical clinic and will be given instructions to hold their AM oral hypoglycemic agent and/or insulin the morning of testing. They will be instructed to eat and utilize their medications in the usual fashion the night prior to testing. After informed consent, baseline blood samples will be obtained for glucose, insulin and c-peptide levels. Patients will then be given a meal of Sustacal HC at 2cc/kg not to exceed 236cc's. Samples will be obtained at 30 and 60 minutes after completion of Sustacal for glucose, insulin and c-peptide. 50 patients are required for the study to include all active duty and dependent patients which meet criteria.

CURRENT AND PRIOR PROGRESS: To date, 52 subjects have been enrolled in the study. All have completed sustacal stimulation and all data has been returned. Preliminary evaluation indicates that peak insulin response after sustacal stimulation is useful in differentiating between type I and type II DM. We continue to track participants to determine the natural history of their disease processes. No complications have occurred with testing.

CONCLUSIONS: Data still being collected. Study ongoing.

REPORT DATE: 1/11/94

PROTOCOL: #93018

Detail Summary Sheet

TITLE: Immunization with a highly purified vaccine
(FSME-IMMUN inject) against tickborne encephalitis:
comparison of an accelerated versus standard schedule

KEYWORDS: tickborne encephalitis, FSME-IMMUN inject

PRINCIPAL INVESTIGATOR: Pittman, Phillip, LTC, MC

DEPARTMENT: USAMRIID
Preventive Medicine

STATUS: Ongoing

APPROVAL DATE: June 1993

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: To make available a thoroughly tested and apparently safe TBE vaccine (FSME-IMMUN inject, IND 1836), currently unlicensed in the U.S., to personnel authorized immunization at Department of Defense affiliated medical treatment facilities or by DOD immunization teams to provide protection against potentially lethal strains of TBE. Intensive observation and specimen collection are impractical in this group. To provide an accelerated vaccination schedule that requires one month instead of 10 months to obtain optimal protection for troops on alert for deployment or already deployed to TBE endemic areas. To compare, in a small group of volunteers under controlled conditions in which more intensive observation and specimen collection can occur, the current (0, 1 month, 9 months) and accelerated (0, 1 weeks, 4 weeks) immunization schedule to define the antibody response to multiple strains of TBE representing predominant strains in different geographic areas.

TECHNICAL APPROACH: This study will have two Parts. Part I will be a small study conducted to compare the standard immunization schedule (0, 1 month, 9 months) with the accelerated schedule (0, 1 week, 4 weeks) in 50 volunteer subjects per group. This will begin as soon as possible to obtain information about kinetics of immune response (seroconversion rate, neutralization and ELISA titer against CEE and RSSE). Part II of the study will vaccinate large numbers of personnel with an accelerated schedule (0, 1, 4 weeks) prior to or during rapid deployment to TBE endemic areas. This arm will be conducted, as required, independent of the immunization schedule comparison arm.

CURRENT AND PRIOR PROGRESS: No patients have been enrolled in this study as of this date.

CONCLUSIONS: None. Study continues.

REPORT DATE: 2/17/94

PROTOCOL: #93019

Detail Summary Sheet

TITLE: Treatment of Adult Patients with Varicella with short course oral Acyclovir.

KEYWORDS: Varicella, Acyclovir

PRINCIPAL INVESTIGATOR: Epperly, Ted, LTC, MC

DEPARTMENT: USUHS
Department of Family Medicine

STATUS: Ongoing

APPROVAL DATE: Sept 93

FUNDING: Current FY: \$ 0 Previous FY: \$ 0 Total: \$ 0

STUDY OBJECTIVE: The objective of this study is to determine if the short course (5 day) oral administration of acyclovir reduces the duration of skin lesions and symptoms of varicella infection in adults. In addition, acyclovir usage will be analyzed to determine if it reduces the length of hospitalization of adult patients, and if it hastens the return to health and duty in a cost effective manner.

TECHNICAL APPROACH: Patients will be randomized into one of two treatment groups. The one group will receive oral acyclovir (800mg five times a day) for 5 days. The other group will receive an identical look-alike placebo given 5 times a day for 5 days. The patients will be followed daily from admission to discharge, and will have all skin lesions counted on a daily basis. 45-50 patients from Fort Bragg and 45-50 patients from Fort Benning will be required to complete the study.

PRIOR AND CURRENT PROGRESS: No patients enrolled in FY93 (study approved by CIC/HUC September 1993).

CONCLUSIONS: None. Study ongoing.

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