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MIPR NO: 92MM2549

TITLE: PROSPECTIVE COLLECTION AND BANKING OF LYMPHOCYTES AND
CLINICAL DATA ON HIV INFECTED INDIVIDUAL TAKING
ANTIRETROVIRAL AGENTS

PRINCIPAL INVESTIGATOR: Richard Harris, LTC, MS

CONTRACTING ORGANIZATION: Fitzsimons Army Medical Center (HSC)
Department of Clinical Investigation
Aurora, Colorado 80045-5001

REPORT DATE: June 1, 1993

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research, Development,
Acquisition and Logistics Command (Provisional),
Fort Detrick, Frederick, Maryland 21702-5012

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FOREWORD

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x *init* For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 45 CFR 46.

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In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

x *init* In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Paul A. Hiri 6-1-93
Principal Investigator's Signature Date

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Banking of lymphocytes and collection of clinical data is successfully progressing with a total 645 patients currently enrolled, 5700 separate data collection times and over 14,000 specimens banked for serum and/or lymphocytes. A poster presentation entitled "THE DURATION OF CLINICAL STABILIZATION WITH AZT THERAPY " D.L. Mayers, L.I. Gardner, R. Harris, R. Pomeranz, D. Cohn, and the Military Medical Consortium for Applied Retroviral Research was accepted for the International HIV conference. The data for this poster was based on analysis of the clinical information obtained from this study.

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Abstract

THE DURATION OF CLINICAL STABILIZATION WITH AZT THERAPY
 S.H. Harrison, D.L. Mayers, L.I. Gardner, R. Harris, R. Pomerantz, D. Cohn, et al.; Military Medical Consortium for Applied Retroviral Research, Rockville, Maryland, United States.

Objective: To determine the rate of clinical progression of HIV disease in patients (pts) who received AZT therapy stratified by the Walter Reed stage (WR) at the time of initiation of therapy.

Methods: 523 HIV-positive pts are followed with serial clinical evaluations at 3 to 6 month intervals. We performed a residence time analysis of the time the patients spent in each WR stage stratified by the WR stage at initiation of AZT therapy.

Results: Table 1. Clinical Progression on AZT Therapy.

WR Stage at Initiation of AZT	Time in Stage WR1/WR2			Time in Stage WR3/WR4			Time in Stage WR5/WR6			Time in Stage WR6 (AIDS)		
	M	m	N	M	m	N	M	m	N	M	m	N
No AZT	1680	502	116	470	267	79	370	363	9	709	370	6
WR1/WR2	1143	112	26	420	318	28	405	405	0	n.a.	n.a.	0
WR3/WR4	346	260	28	739	674	88	206	130	16	216	216	1
WR5	305	242	30	373	339	68	531	466	25	472	383	8
WR6 (AIDS)	222	253	6	451	335	19	159	128	12	704	733	6

*M = mean (days); m = median (days); N = number of patients

Conclusions: The efficacy of AZT to delay clinical disease progression is of limited duration lasting approximately 600 days for patients with > 400 CD4 cells (WR1/2) and approximately 300 days for patients with < 400 CD4 cells (WR3-6). Subsequent clinical progression occurs at similar rates in AZT-treated and AZT-naïve populations by an intention to treat analysis.

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ANNUAL REPORT

1. MIPR No. 92MM2549

2. Report Date: 15 April 1993

3. Reporting Period from: 1 April 1992

to: 31 March 1993

4. P.I.: Richard Harris, LTC, MS

5. Phone #: (303) 361-4042 /DSN 943-4042

6. Agency/ Address: Fitzsimons Army Medical Center
HSHG-CI
Aurora, CO 80045-5001

7. Project Title: Prospective Collection and Banking of Lymphocytes and Clinical Data on HIV Infected Individuals Taking Antiretroviral Agents. FAMC Protocol # 91/300

8. Current Staff, with percentage of effort on each project:

Richard Harris, LTC, MS
Erin Palestro, R.N.

100%

9. MIPR Expenditures to date:

Personnel	\$ 38,615.	Supplies	\$172,561.
Travel	\$ 17,114.	Other	\$ 2,070.
Equipment	\$ 5,991.	Contracts	\$ 3,482.

Total \$239,833.