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)
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**Performing Organization:** Fitzsimons Army Medical Center (HSC) Department of Clinical Investigation Aurora, Colorado 80045-5001

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

**Abstract:**
Banking of lymphocytes and collection of clinical data is successfully progressing with a total of 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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In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

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

In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

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

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

Principal Investigator's Signature Date 6-1-93

94-20947 94 7 8 053
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

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 I: Clinical Progression on AZT Therapy.

<table>
<thead>
<tr>
<th>WR Stage at Initiation of AZT</th>
<th>Time in Stage WR1 (months)</th>
<th>Time in Stage WR2 (months)</th>
<th>Time in Stage WR3 (months)</th>
<th>Time in Stage WR4 (months)</th>
<th>Time in Stage WR5 (months)</th>
<th>Time in Stage WR6 (months)</th>
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<tr>
<td>WR1/WR2</td>
<td>14.1</td>
<td>11.2</td>
<td>24.0</td>
<td>18.0</td>
<td>26.0</td>
<td>18.0</td>
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<tr>
<td>WR3/WR4</td>
<td>13.6</td>
<td>26.0</td>
<td>28.0</td>
<td>21.0</td>
<td>16.0</td>
<td>16.0</td>
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<tr>
<td>WR5/WR6</td>
<td>13.6</td>
<td>24.0</td>
<td>28.0</td>
<td>21.0</td>
<td>16.0</td>
<td>16.0</td>
</tr>
<tr>
<td>WR6 (AIDS)</td>
<td>12.2</td>
<td>23.0</td>
<td>12.0</td>
<td>15.0</td>
<td>12.0</td>
<td>12.0</td>
</tr>
</tbody>
</table>

*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-naive populations by an intention to treat analysis.

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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    100%
   Erin Palestro, R.N.

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.