

INFORMED CONSENT

TITLE OF RESEARCH STUDY:

INDUCED MALARIA as THERAPY for HIV INFECTION

Sponsor: This research study is being funded by The Heimlich Institute Foundation, Inc. to the extent that contributions are received for this specific project beyond the Foundation's administrative and research expenses, in Association with Dr. Wilbert C. Jordan and Dr. Henry Heimlich, the Co-Principal Investigators.

INTRODUCTION

The increasing incidence and the devastating mortality and morbidity of human immunodeficiency virus (HIV) infection have been matched by intense scientific efforts aimed at finding a means to help those infected with HIV and to prevent its spread.

PURPOSE OF STUDY

The purpose of this study is to assess the effectiveness and safety of Induced Malaria Therapy. It is hoped that IMT will cause a substantial reduction in the body's HIV viral load and allow improved immune function. Improvement in immune function may demonstrate itself by beneficial change in CD4 cell numbers, and other monitored markers of immune system function.

DURATION OF STUDY

The duration of the study will be approximately 14 weeks after an initial infusion. You will be required to make a minimum of 12 visits to a physician's office.

STUDY PROCEDURE

You will undergo a medical history and physical examination at study entry. Women of childbearing potential will be tested for pregnancy.

Natural infusion of malaria parasites will be administered on days (*sic*) one. Blood tests will be performed prior to starting treatment: baseline, weekly during febrile response to malaria and three and six weeks after antimalaria treatment has begun.

You may withdraw from the study at any time without jeopardizing your future medical care or possible involvement in subsequent clinical studies.

Your participation may be terminated by the researchers under these circumstances:

1. Deteriorating health or other conditions that might make continued Participation detrimental to your health.
2. Failure to keep appointments for infusion date and blood analysis.
3. Decision by the Investigators to stop the study on medical grounds.
4. Decision to change your anti-retroviral regimen.

RISKS AND DISCOMFORTS

You understand and acknowledge that Induced Malaria Therapy in the treatment of HIV has only been used in a very limited number of human beings for evaluation of treatment of symptoms from HIV/AIDS. There may be discomfort from the infusion of Induced Malaria Therapy and the blood draws. Such discomfort may include pain from the needlestick and/or bruising. You further understand that there is a risk of adverse side effects or complications as a result of your receiving treatment. Such adverse side effects or complications may include, but are not necessarily limited to the following: fever, chills, fatigue, nausea, vomiting, headache, flushing, shortness of breath, tightness of the chest, back pain, muscle aches, sweating, fall in blood pressure, rash, joint pain, muscle weakness, and acute allergic reaction (which could on rare occasions be fatal). There is also a possibility that treatment with Induced Malaria Therapy may accelerate your HIV disease condition.

POTENTIAL BENEFITS

By signing this document, you understand that the research investigators do not guarantee, represent, or warrant that treatment with Induced Malaria Therapy may stop or retard the progress or recurrence of symptoms of AIDS or ARC.

The investigators cannot promise that your participation in this research study will guarantee any direct or immediate benefit to you. However, the Induced Malaria Therapy you receive may benefit you by elevating the total CD4 cell population and/or reduce your HIV viral load. It is hoped that the knowledge gained from this study will be of benefit to others in the future.

Neither Dr. Heimlich nor the Heimlich Institute Foundation, Inc. practices (*sic*) medicine or provide medical care. They are involved in the malariatherapy project solely from the standpoint of evaluating scientific data.

OTHER INFORMATION

In case of any medical problems, side effects or other reactions the patient should contact his or her primary care physician for treatment at the following number:

() _____ - _____.

If it is believed the problem is related to the study, contact the study coordinator:

() _____ - _____.

You realize that the administration of this agent is being done as a pilot study for medical research and there is no commitment by the Principal Investigator to provide access to this modality in the future.

POLICY REGARDING PREGNANCY and CONTRACEPTIVE

You understand that if you are a woman of childbearing age, you will be admitted to the study only if you are not pregnant and if you agree to use a barrier contraceptive or an effective method of birth control for the duration of the study. If you should become pregnant while on this study, you must inform the investigator immediately so that you can be withdrawn from the study. Your physician will recommend an alternative therapy to you with respect to your health and that of your unborn child. You understand that all participants should use barrier contraceptive methods.

CONFIDENTIALITY

You understand that all information will be held confidential and will not be released without your written permission. Furthermore, you understand that your records and results will not be identified in any publications as pertaining to you specifically. You will be identified only by a code number for the purposes of the study, known only to the study personnel. You understand that you will also be giving consent for the Principal Investigator to review your medical records as may be necessary for the purpose of this study.

CONSENT

You understand that you have the right to request the Principal Investigator and/or your physician to (*sic*) answer any and all questions you might have concerning this therapy at any time prior to or during the course of the study. You understand that you have the absolute right to terminate your participation in this study at any point during its course.

You hereby agree to hold harmless the Heimlich Institute, Dr. Wilbert Jordan, Dr. Henry Heimlich, and all other health care providers involved in any way in this study.

You understand that the use of Induced Malaria Therapy is on an experimental basis, and that this treatment has not been approved for use by the FDA or any other governmental agency. You voluntarily accept all risks associated with the use of the product, known or unknown. You understand that this agreement is binding on you, your estate, your heirs and assigns, and extends to all liability of any nature whatsoever, including any claim for negligence or failure to warn. You hereby bind yourself, your estate, your heirs and assigns, and any person or entity claiming to act on your behalf or on behalf of your estate, your heirs or assigns, not to make any claim against any person or entity whatsoever, for anything of value, arising out of the use, manufacture or distribution of this product.

Your signature indicates that you have read and understand this consent form. You have decided to participate in this research study. You have received a copy of this informed consent. You understand the nature of the study, the procedures, the benefits, and the risks.

I have had an opportunity to ask questions and have all responses explained to you (*sic*) by the Principal Investigator in a language I understand.

I freely agree to enroll in this study having read, in detail, this Informed Consent Form

Name of Patient (Please Print)

Address of Patient

(____) _____ - _____
Phone Number of Patient

Signature of Patient

____ / ____ / ____
Date

Name of Witness (Please Print)

Signature of Witness

____ / ____ / ____
Date

Name of Investigator (Please Print)

Signature of Investigator

____ / ____ / ____
Date