INSTITUTE: National Cancer Institute

STUDY NUMBER: 13-C-0118 PRINCIPAL INVESTIGATOR: A. P. Chen, M.D.

STUDY TITLE: A Phase I Trial of TRC102 (methoxyamine HCl) in Combination with Temozolomide in Patients with Relapsed Solid Tumors and Lymphomas

Continuing Review Approved by the IRB on 06/26/18
Amendment Approved by the IRB on 05/07/19 (S) Date Posted to Web: 06/08/19

Healthy blood donor

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary**.** You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation. You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss *this study* with anyone at NIH, or with family, friends or your personal physician or other health professional.

Why is this study being done?

We are doing this study to collect blood from healthy volunteers as part of a study at the NIH to develop better treatments for patients with cancer. This protocol provides a way to collect healthy blood samples. You will not be given any experimental drugs on this study.

Why are you being asked to take part in this study?

Before you enrolled in this protocol, you confirmed that you are a healthy volunteer interested in taking part in a sample procurement protocol. Please understand that no attempt will be made at comprehensive medical evaluation to confirm this, and that taking part on this laboratory research study must not be a substitute for routine or indicated medical care from your own physician. You will not be asked to take part if your hemoglobin levels are too low or you are on any medication that might affect how your red blood cells work.

How many people will take part in this study?

Up to 10 healthy volunteers can participate in this study.

What will happen if you take part in this research study?

Before you begin the study

If you have not already done so, you must register with the NIH Clinical Center. This involves providing a limited amount of demographic and contact information. Once that information is entered into the Clinical Center Information system, a medical record number can be assigned. You will also be asked to visit the admissions department, where you will sign a General Admission Consent and an Information Practices form. Registration should take no more than 10 minutes, and you must do it only once.

Donation of a blood sample

You will be asked to donate up to 4 tablespoons of blood during sample collection. The blood sample will be removed from a vein in your arm. This procedure is no different than having blood drawn for any clinical test. We may collect one blood sample from you at each study visit at which you agree to give a sample.

How long will you take part in this research study?

Your participation on this protocol will continue until you withdraw from the study or the study is closed, at which time your participation will end.

Will the test results be shared with you?

The results of our research studies will not be provided to you or your physician. The results from studies on the research samples may be published, but individual blood donors will not be identified in the publications.

What happens when the research study is over?

When the protocol is closed, data and sample analysis will continue for some time. Your samples will be kept until they are no longer of scientific value, at which time they will be destroyed.

What types of studies are we doing?

If you choose to take part, your donated blood samples will be used only for laboratory experiments. Your samples will not be examined by a pathologist or used for diagnostic purposes. Laboratory research studies help us improve our understanding of cancer and may help us improve our understanding of the normal process of blood cell production. The results from samples donated by healthy volunteers will be compared with the results from samples donated by patients with cancer.

Risks or Discomforts of Participation

What possible risks can I expect from taking part in this study?

Related to blood sampling:
Side effects of blood sampling include pain and bruising in the area where the blood was drawn, lightheadedness, or rarely, fainting due to transient lowering of blood pressure. If you feel dizzy, you should lie down for a few minutes to avoid hurting yourself if you fall. Infection at the blood-drawing site could also occur.

Where will your research sample be stored?
Research samples are stored in our laboratory, under the care and supervision of the investigators on this protocol. The samples are stored without any personal identifying information, meaning that these samples could never be traced back to you.

Who will have access to the study findings?
No other individual, including your spouse, parent, children, referring physician, or employer, will have access to the stored samples.

Will you ever be able to benefit economically from donating your sample to this study?
You will not be compensated for giving blood samples on this study. Your research samples will not be sold to anyone. However, commercial products that may later help others improve the diagnosis and treatment of various medical conditions may be developed and patented based on our research. You and or your heirs will not be compensated should this occur.

What are the potential benefits of participation?
It is very unlikely that what we learn from these studies will have a direct benefit to you. The knowledge gained from this study may help others in the future who have cancer.

Alternative treatments
This is not a treatment protocol, so there are no alternative treatments, other than to choose not to take part.

Conflict of Interest

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a Protocol Review Guide. You may ask your research team for a copy of the Protocol Review Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines but they do not need to report their personal finances to the NIH.

Will my medical information be kept private?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at: 1-800-4-CANCER (1-800-422-6237). You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. If you want more information about this study, ask your study doctor.

OTHER PERTINENT INFORMATION

1. **Confidentiality.** When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

   The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. **Policy Regarding Research-Related Injuries.** The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. **Payments.** The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. **Problems or Questions.** If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Dr. Alice Chen, 31 Center Drive, Building 31, room 3A44, Bethesda, Maryland, Telephone: 240-781-3320. You may also call the Clinical Center Patient Representative at (301) 496-2626.

5. **Consent Document.** Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:	
A. Adult Patient's Consent I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study. _____ Signature of Adult Patient/Legal Representative Date _____ Print Name	**B. Parent's Permission for Minor Patient.** I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.) _____ _____ Signature of Parent(s)/Guardian Date _____ Print Name
C. Child's Verbal Assent (If Applicable) The information in the above consent was described to my child and my child agrees to participate in the study. _____ _____ _____ Signature of Parent(s)/Guardian Date Print Name	
THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM JUNE 26, 2018 THROUGH JULY 23, 2019. _____ _____ _____ _____ Signature of Investigator Date Signature of Witness Date _____ _____ Print Name Print Name	