Experimental Subject's Bill of Rights

The California Health and Safety Code requires that any potential research subject (or their guardian) be provided with this list of subject's rights. This sheet should be signed and dated before consent is given to participate in any medical research.

Any person who is asked to consent to participate as a subject in a research study involving a medical experiment, or who is asked to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.
3. Be given a description of any possible discomforts and risks that may be expected from the experiment.
4. Be given an explanation of any benefits they may reasonably to be able to expect from the experiment, if applicable.
5. Be told of any appropriate alternative procedures, drugs, or devices that might help the subject, and the possible risks and benefits of these other options.
6. Be informed of how to get medical treatment, if any is needed, after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or other procedures involved.
8. Be instructed that their willingness (or consent) to participate in the medical experiment may be withdrawn at any time, and the subject may stop participation in the medical experiment without any prejudice towards them or their being able to access healthcare if needed.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

_____ _____

Subject's Signature Date

_____

Printed Name of Subject

_____ _____

Witness's Signature Date

IRB Approved Through:
5/5/23 QB
Date Initials

INFORMED CONSENT FORM

Title of the study: Absorption of Glutathione Given Topically Using Glutaryl™

Invitation to Participate:

You are invited to participate in a study to evaluate the effects of Glutaryl™ Spray. Glutaryl™ is a supplement supplying an antioxidant called glutathione (GSH) in nanoparticle suspended liquid. All of the components of the product are natural and composed of material considered GRAS (Generally Recognized as Safe) by FDA. You have been selected because you are healthy, and you are between 21 and 65 years of age. A total of 30 subjects will be participating in this pilot study.

Why we are doing this research and how much time it will take you

GSH is a natural antioxidant that serves important functions in maintaining immune health. The overall purpose of the study is to determine if the topical application of Glutaryl™ spray will increase the levels of GSH, along with a decrease in the levels of free radicals (harmful chemicals produced by the body) leading to changes in the levels of proteins called cytokines that enhances the immune response. This study will provide us with insight into the effectiveness of a new, simple approach that can further enhance the level of GSH antioxidants in the body and improve immune function.

The goal of this comparative, pre/posttest study is to determine the following in healthy adult volunteers ages 21-65 recruited at WesternU Pomona:

1 Will Glutaryl spray treatment in a nanoparticle formulation applied trans-dermally to the abdomen exceed baseline measures and increase the serum level of GSH to a therapeutic level of 2-5 uM?

2 Will free radicals (malondialdehyde) levels in the plasma and blood cells decrease to reach a therapeutic level of 100nM?

3 Will the levels of pro-inflammatory cytokines in the plasma and blood cells increase to reach a therapeutic level of above 50pg/ml?

4 Will the levels of anti-inflammatory cytokines in the plasma and blood cells decrease to reach a therapeutic level of 5ng/ml?

5 Will participants receive direct therapeutic benefit as measured by improved immune cells functions to control M.avium infection.?

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The study will take 3 days to complete and will be conducted at the Western University Patient Care Center (PCC) and Rodney P. Weinberg Center (RWC) in Pomona, CA. Participants will report to Western University Patient Center (PCC) only. The trial will take 4.5 hours the first day of testing. During the first day, we will draw blood 30 minutes prior to the first spray, 1 hour after the first spray, and 4 hours after the first spray for a total of 3 blood draws the first day. Participants will be given the option to leave in between blood draws. Those who choose to leave will have to report back in time for the next blood draw. After 72 hours of the first spray, participants will again report to PCC where they will get their blood drawn once and they will be able to leave after. Throughout the study, each participant will have a total of 4 blood draws. Participants may be tested on different days as they will be recruited throughout the duration of study.

This pilot study will determine the levels of GSH, free radicals and cytokines in the plasma and blood cells isolated from healthy subjects. There will be a control group (receives Placebo treatment) and experimental group (receives Glutaryl™ spray treatment). Given that GSH is available as a supplement for humans and has been widely used, we propose to study the effects of topically applied Glutaryl™ spray in increasing the levels of GSH thereby decreasing the concentration of free radicals in the plasma and blood cells from healthy subjects.

Description of the procedures:

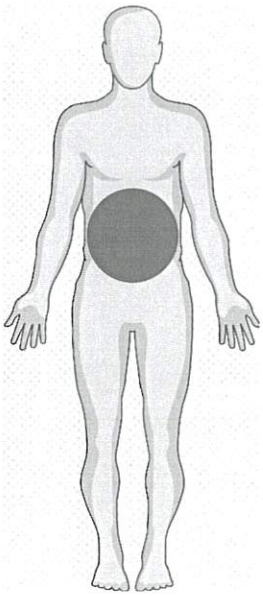
If you are interested in participating in this study, you will first meet with Drs. Venketaraman, Yutani and/or Ochoa. During this initial meeting, we will draw two tubes of blood from you for clinical lab tests (complete metabolic panel, HIV, and latent TB) to confirm that you are healthy. If your results are normal, you will be allowed to continue in the study. If your lab results are abnormal, you will be excluded from the study and Dr. Yutani or Ochoa will provide medical advice.

If you continue in the study, you will be given a spray that is either Glutaryl™ or placebo. You will not know which spray you have received, and neither will we. You will spray the front of your abdomen 4 times. You will perform this procedure twice a day with at least 6 hours in between each set of sprays. Please repeat this procedure for 3 days in a row.

A total of 4 blood draws will take place throughout the study. You will need to be in the lab the first day for 4.5 hours. We will draw 1 tube of blood (5 mL) 30 minutes prior to the first spray, 1 tube of blood (5 mL) 1 hour after the first spray, and 1 tube of blood (5 mL) 4 hours after the first spray. You will need to return to the lab 3 days after your first spray and we will draw 1 final tube of blood (5 mL). We will draw blood from a vein in the arm and will test it in the research laboratory of Dr. Venketaraman for the levels of the antioxidant GSH, free radicals and cytokines. The timing of blood draws will be made in reference only to the first spray on the first day of the trial. We will test the blood we

collected from you for the levels of antioxidant (glutathione), free radicals (malondialdehyde) and certain types of immune proteins (pro- and anti-inflammatory cytokines).

The image below shows the area of the abdomen where you can spray yourself.



Potential Risks and Discomforts:

The blood drawing will pose a minimal risk of bruising, like any blood drawing procedure. You may also feel weak, faint, or dizzy. Refreshments (juice, water, and snacks) and a rest area will be offered to participants feeling dizziness. We will contact 911 in case of further complications. Standard size needles will be used, and other gauge sizes are available as necessary with the advice of medical professionals on site. All blood drawing will be done by experienced personnel Drs. Cesar Ochoa and Ray Yutani at the WesternU Medical Center to reduce your risk of discomfort.

During the pre-screening appointment, the clinician will take vital measurements, perform a physical exam, symptom, and medication review to assess for potential reaction. Furthermore, the application site of glutathione will be rotated between the right and the left side of the abdomen to avoid contact rash. If any minor rash develops, glutathione application will be stopped immediately, and the rash should subside within a few hours. The topical application of the spray may present with signs of skin whitening or discoloration.

There is always a small risk of loss of your confidential data. To decrease these risks, we will increase patient confidentiality measures at all levels of participation. We will only collect the data we need and will use study-specific identification numbers that do not identify you. Any secure and confidential files will be stored in locked cabinets in the office

of the Primary Investigator, Dr. Venketaraman, located in the HEC building room #2220. The records will be kept for 5 years from the date of start of the study and then securely destroyed.

Potential Benefits:

You may not experience any direct benefit from participating in this study, but the . findings from this study will help us better understand how well this formulation of glutathione works and whether it has a positive effect on immune function. If it does, it could benefit society by offering other options for treating immune diseases and managing complications from glutathione deficiency.

Alternatives to Participation:

No alternative treatments will be offered in place of the experimental procedure, so the only alternative is non-participation in the study.

Compensation for Participation:

Subjects who participate in this study will receive a total of $50 upon completion of the study for their participation.

Assurance of Confidentiality:

No information obtained in connection with this study can identify you, except for this informed consent. Participants are assigned a number that is only known to the primary investigator. No information about you or your participation will be released in any manner. However, your records may be inspected by state or federal regulatory agencies. Data will be presented as a summary of all subjects enrolled in this study.

Data and records created by this project are the property of the university and the investigator. You may have access to information collected on or about you by making a written request to the principal investigator, Dr. Venketaraman. This right of access extends only to information collected on or about you and not to information collected on or about others participating in the study.

We do not anticipate using the protected health information (PHI) that you will be providing. Should the PHI be used, we will comply with the rules and regulations concerning the privacy and security of PHI under the federal Health Insurance Portability and Accountability act (HIPAA) of 1996.

Statement of Injury or Special Costs:

In the event that this research activity results in an injury, you should contact Dr. Vishwanath Venketaraman at (909) 706-3736, or Dr. Ray Yutani at (909) 469-5499. Treatment will be available, including first aid, emergency treatment and follow-up care as needed. You and your third-party payer (such as insurance or Medicare) must provide payment for any such treatment. This paragraph does not mean that you are releasing or waiving any legal right you might otherwise have against WESTERNU as a result of your participation in this research activity.

Offer to Answer Questions:

You should feel free to ask questions now or at any time during the study. If you have any questions about this study, you can contact Drs. Venketaraman or Dr. Ray Yutani. If you have questions about the rights of research subjects, contact the WESTERNU IRB Office at (909) 469-5636.

Withdrawal from the Study:

Your participation is voluntary. Your decision whether to participate will not affect your present or future relationship with the university. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time, though any blood samples collected, and data derived from them will remain property of the investigators.

Source of Funding:

Auro Pharmaceuticals has agreed to gift the Venketaraman lab $45,000 in an unrestricted gift payment and $4,000 in materials and products for this research.

Consent Statement:

You are voluntarily making a decision whether or not to participate. Your signature indicates that you have decided to participate, having read the information provided above. You will be given a copy of this consent form to keep.

I have read this information, which is printed in English. This is a language that I read and understand.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

_____

Printed Name of Consenting Investigator

_____ _____

Signature of Consenting Investigator Date

IRB Approved Through:
5/5/23 JB
Date Initials

CLINICAL TRIAL TO IMPROVE IMMUNE HEALTH

We are looking for healthy participants to test a new glutathione skin spray called Glutaryl to see if it improves the immune system.

The goal of this comparative, pre/posttest study is to determine the following in healthy adult volunteers ages 21-65 recruited at WesternU Pomona:

1 Will Glutaryl spray treatment in a nanoparticle formulation applied trans-dermally to the abdomen exceed baseline measures and increase the serum level of GSH to a therapeutic level of 2-5 uM?

2 Will free radicals (malondialdehyde) levels in the plasma and blood cells decrease to reach a therapeutic level of 100nM?

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5 Will participants receive direct therapeutic benefit as measured by improved immune cells functions to control M.avium infection.?

GLUTATHIONE

A natural antioxidant that has been shown to improve immune responses against known pathogens such as Tuberculosis. Our past studies in HIV and type 2 diabetes patients demonstrated that glutathione improved the immune system response.

BENEFITS OF GLUTATHIONE

-Natural Antioxidant
-Shown to improve immune response against pathogens
-Prevents cellular damage
-Safe
-Reduces harmful free radicals in the body

CURRENT STUDY

We will evaluate the effects of topical Glutaryl spray on healthy participants. Participants will be randomly assigned either a glutathione spray or placebo spray. Participants will adhere to the following protocol:

-Dosage: 4 sprays
-Frequency: Twice daily
-Duration: 3 days

Participants will have blood drawn 4 times to test the levels of glutathione and other immune markers in your blood

ARE YOU ELIGIBLE?

We are seeking healthy individuals with no history of TB, HIV, or liver function abnormalities.

CONTACT INFORMATION

Please contact the Venketaraman lab for more information or if you want to participate in this study.

(vvenketaraman@westernu.edu)