

**Statement of Informed Consent:
Exogenous Testosterone and venous thrombosis in Patients with Underlying
Clotting abnormalities**

1. Introduction

When men are given exogenous testosterone because of reduced libido and/or low serum free testosterone, and/or reduced testicular function due to diseases, some of the testosterone is chemically changed in the body to the hormone estradiol. The percent conversion to estradiol is not well understood, and it is also not well understood whether the degree of conversion to estradiol affects libido or sexual performance.

In some men, when given exogenous testosterone, the estradiol which is produced interacts with underlying inherited clotting abnormalities to produce blood clots, including clots in the legs, the lungs, the eyes, etc.

We plan to study two groups of men, as follows:

- a. Men given conventional androge/ Testosterone for purpose of libido enhancement and hypogonadism.
- b. Men who sustained blood clots who had been on androge/Testosterone

2. Objectives

First, we will obtain important information about changes in total and free testosterone and estradiol in the blood in men given exogenous androgens for libido, and/or low serum free testosterone, and/or reduced testicular function due to diseases.

Second, we will obtain very important clinical information to understand why some men develop blood clots after being given exogenous androgens. The study will open new doors in studying the relationship of exogenous testosterone with thrombosis and complications from thrombosis. The better understanding of the disease process will help prevent these complications in people receiving exogenous testosterone in the near future. We hypothesize that giving exogenous testosterone to patients with underlying clotting abnormalities increases their chances of getting venous thrombosis by the conversion of testosterone to estradiol in the body, and the interaction of that estradiol with clotting factors in the blood.

3. Procedures

Working in concert with Jewish Hospital associated urologists, and with self referred men from our Website, in otherwise healthy men about to receive exogenous androgens, we will obtain a blood sample before administration of the exogenous androgens and after 2 months on androgen therapy. The measurement of serum total and free testosterone and estradiol levels will be free of charge.

Using the Jewish Hospital Cholesterol Center Website to describe our protocol, we will invite men who have sustained thrombotic events while taking exogenous androgens to have measurements of coagulation abnormalities while still taking the exogenous androgens. Given

the expense of the coagulation evaluation, we will ask that third party payers cover the cost of the coagulation assessment. Our clinical evaluation, and measurement of total and free testosterone and estradiol will be free of charge.

All subjects will have measurements of total and free testosterone and estradiol levels.

At study entry, a detailed medical history will be taken. All medications, smoking history, exercise history will also be recorded. In those patients having sustained thrombotic events, previous laboratory measurements and doctors' records will be sought.

4. Exclusion Criteria

Patients with known prostate cancer which might be worsened by exogenous androgens.

5. Risks and Precautions

Risks/discomforts may be as follows:

I have been told that the study described above may involve the following risks and/or discomforts and safeguards and/or precautions to avoid them.

The only potential risk will be discomfort of having blood drawn (total 30 ml). The blood drawn in the study are the same which would routinely be drawn.

6. Potential Benefits

Patients receiving therapeutic exogenous androgens for libido and/or sexual performance issues will get measures of serum free and total testosterone and estradiol before and on therapy. This information will be valuable in guiding the dose of future therapy, and in assessing the efficacy of therapy.

Patients having clotting abnormalities, receiving exogenous testosterone and subsequently developing thrombosis will be checked for their blood total and free testosterone and estradiol levels. The study will open new doors in studying the relationship of exogenous testosterone with thrombosis and complications from thrombosis. The better understanding of the disease process will help prevent these complications in people receiving exogenous testosterone in near future.

7. Right of Refusal

Participation in this study is voluntary. If you refuse to participate, there will be no penalty or loss of any benefit to which you are entitled. If you volunteer to participate in the study, you may withdraw from the study at any time without a penalty or loss of any benefit to which you are entitled.

8. Confidentiality

Your medical records will be treated as confidential. Only authorized personnel (Dr CJ Glueck) and his designated Cholesterol Center Research Personnel will have access to the records. It is possible that an authorized person from the department of Health and Human services, Food and Drug Administration (FDA) or other federal agency will inspect the records. In all instances except the FDA, your name will remain confidential, as will all laboratory and clinical results. In the case of a new drug administration the FDA does have a right to know your name and this may be revealed to the proper authorities from the FDA if requested to do so. With the exception of Dr CJ Glueck and his designated Cholesterol Center Research Personnel, no one will be permitted to examine your records without your written consent.

Results of your laboratory tests, and results of your evaluation at the cholesterol center will only be released with your written original signature consent, and will only be released to health care professionals responsible for your care.

9. Costs to the subject There will be no additional physician, nutrition, or laboratory charges other than charged for the routine visit.

11. Availability of Information

Any question that you may have concerning any aspect of this study or your rights as a subject in the study will be answered by: Dr CJ Glueck. MD, Phone 513-585-7800, Fax 513-585-7950, email: glueckch@healthall.com

The Jewish Hospital of Cincinnati follows a policy of making all the decisions concerning compensation and medical treatment for injuries occurring during or caused by participation in biomedical or behavioral research on an individual basis. If believe I have been injured as result of research or have questions about my rights as a research subject, I will contact Stephen Goldberg, MD, Chairperson, IRB. Phone 513-686-5446

CONSENT

I, _____, HAVE READ AND UNDERSTOOD THE PRECEDING EXPLANATION, AND I CONSENT TO PARTICIPATE IN THE STUDY AS DESCRIBED ABOVE ON SECTION 2 CAPTIONED " OBJECTIVES". I CONSENT TO THE PROCEDURES DESCRIBED IN SECTION 3 CAPTIONED "PROCEDURES". I UNDERSTAND THAT I AM FREE TO WITHDRAW WITHOUT PENALTY OR LOSS OF BENEFIT FROM THIS INVESTIGATION AT ANY

TIME. SHOULD I WISH TO WITHDRAW I HAVE BEEN ASSURED THAT STANDARD THERAPY FOR MY CONDITION WILL REMAIN AVAILABLE TO ME. I HAVE BEEN INFORMED OF THE PROBABLE CONSEQUENCES OF MY WITHDRAWL FROM THE STUDY.

SUBJECT: _____ DATE: _____

INVESTIGATOR: _____ DATE: _____

WITNESS: _____ DATE: _____