

Informed consent for Participation in Research

INTRODUCTION:

By signing this form you have voluntarily agreed to participate in a research study entitled:

A randomized placebo-controlled trial of dehydroepiandrosterone (DHEA) treatment for four months before starting ovulation induction for in vitro fertilization (IVF)

To be carried out under the supervision of: David H. Barad, MD MS

Principal Investigator: David H. Barad, MD MS
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CONFIDENTIALITY

The study research records will be kept confidential and you will not be identified in any written or verbal reports. The research records will be kept in a secure password protected computer file. Any paper records related to this study will be locked in a file cabinet in the research offices of the Principal Investigator. Research personnel authorized by the Principal Investigator will have access to these records.

Your research records may be inspected by members of the research team, and the sponsors of this research.

Your records may also be inspected by the human research committee of CHR.

WHOM TO CONTACT FOR QUESTIONS:

- You can call the supervisor of this study, named at the beginning of this consent document in the introductory paragraph.

STUDY SPECIFICS

1. PURPOSE:

When attempting in-vitro fertilization (IVF), older women produce few oocytes and yield few normal embryos. As a result few women over 40 years old become successfully pregnant with IVF treatment. Based on our review of the literature and on our recent clinical experience, we believe that pre-treatment with dehydroepiandrosterone (DHEA), a nutritional supplement, may improve the

response to ovulation induction, and possibly improve embryo quality and chances of pregnancy.

The purpose of this research project is to *test* if women with evidence of decreased ovarian reserve who are treated with DHEA for four months will improve their response to ovulation induction, compared to women who were using a placebo.

2. PROCEDURES:

Women who present for infertility treatment by in vitro fertilization will be asked to sign informed consent, undergo baseline study and then be randomized to 2 treatment groups. Group 1: DHEA, Group 2: Placebo. Treatment will continue for 4 months, with continuing observation as described in the protocol. After four months of treatment the participants will undergo their planned in-vitro fertilization treatment.

3. RISKS:

- DHEA may elevate levels of testosterone -- and dehydrotestosterone (DHT) in hair follicles. An elevated level of DHT may cause hair loss in some people.
- Possible side effects associated with DHEA use are acne, deepening voice and facial hair growth, though long-term effects of DHEA administration are unknown.
- Other possible DHEA side effects include menstrual irregularities, irritability and restlessness.
- As a precursor of sex steroids one, of course, has to be concerned about the potential effect on hormone-sensitive malignancies. Women with a history of breast cancer or endometrial cancer should not take DHEA.
- There have been some recorded instances where people who take large doses of DHEA notice irregular heartbeats and heart palpitations.
- Serious adverse effects, such as blood clots are extremely uncommon at such dosages, while dosages as high as 1600 mg daily have caused significant side effects, requiring discontinuation of treatment

4. BENEFITS:

- *Potential benefits to you:*
 - If you choose to participate in this study and are randomized to the group of women who will use DHEA pretreatment, you may experience improved ovarian response during ovulation induction for your IVF cycle resulting in increased yields of eggs and embryos and possible improved chances of pregnancy.
 - Other investigators have reported that DHEA may have beneficial effects on: aging, heart disease, lupus and other forms of arthritis, improved libido, improved mood and decreased depression. Few of these claims are substantiated by formal research.
- *Potential benefits to others:*
 - Your participation in this research project may result in the potential benefits to other infertile women but no benefit to yourself.

5. ALTERNATIVES:

You may choose not to participate in this study, in which case you would be able to start your IVF treatment sooner. You may also choose to use DHEA dietary supplementation on your own, since it is available in a non-prescription form at most pharmacies.

COSTS TO SUBJECTS:

You, or your participating insurance company, will be billed for the full cost of your planned IVF cycle, and for normal charges incurred in preparation for that cycle.

You will not be charged for procedures performed that are purely related to your participation in this study.

REASONS FOR TERMINATION:

We will be monitoring you while you are participating in the study for evidence of side effects. If we feel that you are experiencing any serious adverse effect of treatment that is attributable to using DHEA we will ask you to stop taking your study pills.

An independent reviewer will monitor the course of this study while it is in progress. If there is significant evidence of benefit or harm before the planned termination of the trial we may end the study prematurely, and give you the option to continue the treatment of your choice, based on the study findings.

WITHDRAWAL:

Your participation in this study is voluntary. You may be a participant in it only if you wish, and you may withdraw from the study at any time. Your relationship with doctors, administrators, employers and staff at this office involved in this study, now and in the future, will not be affected in any way if you refuse to participate or if you enter the program and withdraw later.

SUMMARY:

The information in this Informed Consent Document has been explained and discussed with you and/or read to you. You have also been given the opportunity to ask questions about this research and have your questions answered. A copy of this consent document has been given to you, whether or not you have agreed to participate in this study.

Signature of Participant

Date

Signature of Husband or other Family Member (when applicable) Date

Signature of Person Reading and Obtaining this Consent

Date