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Does dehydroepiandrosterone (DHEA) improve IVF outcomes in poor responders?

Submission date
26/04/2013

Recruitment status
No longer recruiting

Registration date
29/10/2013

Overall study status
Completed

Last Edited
01/02/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
One in seven couples have difficulty conceiving despite regular unprotected sexual intercourse. Some of these couples will end up having medical assistance to get pregnant, often in the form of in-vitro fertilisation (IVF/test-tube babies). This will include couples with or without medical problems making natural conception difficult or impossible and those who cannot fall pregnant naturally e.g. same sex couples. The aim of IVF is to assist women to produce many eggs, remove the eggs surgically and fertilise them outside the body using her husband's or donor sperm; transferring one or more of the resulting embryos (fertilised eggs) to her womb to develop as a baby. One of the factors that determine the success of IVF is how many eggs are produced, as this will determine how many embryos are created and allow the best embryos to be selected for transfer to the womb. Some women tend either not to respond to the drugs that cause egg production during IVF or produce very few eggs and are termed poor responders. Often their IVF treatment is either unsuccessful or stopped and it can be very distressing for all involved. Dehydroepiandrosterone (DHEA) is a naturally occurring hormone that is thought to increase the number of eggs produced by these women when given before and during their IVF treatment. There has been no properly conducted research to test whether this is actually true and that is what we propose to do. We aim to study whether pregnancy rates are improved after IVF in poor responders when given DHEA. We will also look at the number of eggs the produce, the quality of their embryos as well as how many of their pregnancies result in a live birth or miscarriage.

Who can participate?
Women who meet an internationally agreed consensus definition of poor responders having IVF at our centre who agree to take part in the study. The women will have any two of the following:
1. Advanced maternal age (≥40 years) or any other risk factor for poor ovarian response (POR)
2. Previous poor ovarian response
3. An abnormal ovarian reserve test

What does the study involve?
Two groups of poor responders going through IVF (200 in each group) will be studied. One group will be given 75 mg DHEA daily and the other a placebo (dummy tablet) to take for 10 weeks before their IVF. Patients will be assigned to the groups at random and neither they nor

the researchers will know which medication they are taking. There will be no change to their IVF treatment. We will follow their treatment and compare the number of women in each group who get pregnant.

What are the possible benefits and risks of participating?
The main benefit of the study is to provide a definitive answer whether DHEA make a difference in IVF outcome in this group of women. If the claims about the effects of DHEA are true, then those in the group taking it, and in the broader context many poor responder women, will benefit by getting pregnant. If the claims are not proven then again many poor responder women will be spared the financial and emotional cost of using an ineffective drug. As far as we can tell from our reading, DHEA is safe at the dose and duration that we will be using it. Several women have used it with no reported significant risk.

Where is the study run from?
1. Homerton Fertility Centre London (UK)
2. The Leeds Centre for Reproductive Medicine (UK)
3. Oxford Fertility, Institute of Reproductive Sciences (UK)
4. Hewitt Fertility Centre at Liverpool Women's NHS Foundation Trust (UK)
5. Glasgow Royal Infirmary (UK)
6. Complete Fertility Southampton (UK)

When is the study starting and how long is it expected to run for?
The study is expected to start recruiting in August 2017 for two years. The trial will end one year after the last baby is delivered.

Who is funding the study?
Homerton University Hospital NHS Foundation Trust (UK)

Who is the main contact?
Professor Roy Homburg
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Contact information

Type(s)
Scientific

Contact name
Prof Roy Homburg

Contact details
Homerton Fertility Centre
Homerton Row
London
United Kingdom
E9 6SR

Additional identifiers

EudraCT/CTIS number

2013-001661-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FE 1202

Study information

Scientific Title
Does dehydroepiandrosterone (DHEA) improve IVF outcomes in poor responders? A randomised, double-blind, placebo-controlled trial

Study objectives
A randomised, double-blind, placebo-controlled trial of 400 poor responders (200 in each arm) to assess the effect of 75 mg DHEA given for 10 weeks prior to ovarian stimulation on clinical pregnancy rate, oocyte retrieval, embryo numbers and quality, miscarriage rates and live birth rate after IVF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/10/2016

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Infertility

Interventions

Controlled ovarian hyperstimulation and in-vitro fertilisation. Two groups of poor responders going through IVF (200 in each group).
Intervention: 75 mg DHEA daily
Control: placebo to take for 10 weeks before their IVF

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Clinical pregnancy rates (ultrasound confirmation of a foetus with a heartbeat at 6-8 weeks gestation)

Secondary outcome measures
1. Ovarian reserve defined AMH levels before and after ten weeks of DHEA supplementation
2. Number of eggs retrieved
3. Number and quality (grade) of embryos available for transfer/freezing
4. Ongoing pregnancies after 14 weeks gestation (miscarriage rates)

Overall study start date
03/06/2013

Completion date
31/12/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 24/10/2017:
Inclusion criteria are based on the ESHRE definition of poor responders and would include any patient with any two of the following:
1. Age ≥ 40 years
2. Markers for poor ovarian reserve (AMH <7 pmol/L(<1.1 ng/ml) and/or AFC< 7)
3. Previous poor response to ovarian stimulation (≤3 oocytes with a conventional stimulation protocol)

Previous inclusion criteria:
European Society of Human Reproduction and Embryology (ESHRE) criteria for poor responders:
1. Age > 40 years
2. Markers for poor ovarian reserve [Anti-Mullerian Hormone (AMH) < 0.5 ng/ml (5 pmol/L), Follicle-Stimulating Hormone (FSH) > 15 IU, Antral Follicle Counts (AFC) < 6]
3. Previous poor response to ovarian stimulation (less than three mature follicles on day of hCG trigger/cycle cancellation due to poor response/less than three oocytes retrieved)

Participant type(s)
Patient

Age group

Adult

Sex
Female

Target number of participants
400 patients (200 in each arm)

Key exclusion criteria
Current exclusion criteria as of 24/10/2017:
1. Women 42 years
2. Women with premature ovarian failure/premature menopause (FSH>40 U/L)
3. Women already taking DHEA.
4. Patients with a known allergy to the trial drug or any of the active ingredients in the placebo

Previous exclusion criteria:
1. Women > 42 years
2. Women with premature ovarian failure/premature menopause (FSH > 40 U/L)

Date of first enrolment
25/08/2017

Date of final enrolment
25/08/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Homerton Fertility Centre
London
United Kingdom
E9 6SR

Study participating centre
The Leeds Centre for Reproductive Medicine
Leeds
United Kingdom
LS14 6UH

Study participating centre
Oxford Fertility, Institute of Reproductive Sciences
Oxford
United Kingdom
OX4 2HW

Study participating centre
Hewitt Fertility Centre at Liverpool Women's NHS Foundation Trust
Liverpool
United Kingdom
L8 7SS

Study participating centre
Glasgow Royal Infirmary
Glasgow
United Kingdom
G4 0SF

Study participating centre
Complete Fertility Southampton
Southampton
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SO16 5YA

Sponsor information

Organisation
Homerton University Hospital NHS Foundation Trust (UK)

Sponsor details
R&D Department
Homerton Row
London
England
United Kingdom
E9 6SR

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/01zpp3d44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Homerton University Hospital NHS Foundation Trust (UK), R&D Number FE1202

Results and Publications

Publication and dissemination plan
Will be provided in scientific journal and presented at meetings.

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration