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A new treatment protocol reducing the risk of implantation failure and early pregnancy loss after transfer of embryos resulting from in vitro fertilisation

Submission date
06/06/2018

Recruitment status
No longer recruiting

Registration date
05/07/2018

Overall study status
Completed

Last Edited
04/07/2018

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
In some cases of infertility, fertilisation and the early post-fertilisation development occur normally, but the resulting embryos fail to implant in the uterus (womb). This problem can be caused by insufficient production of the hormone called progesterone by the ovary. This abnormality is often associated with hormonal treatment protocols used for in vitro fertilisation (IVF). To solve this problem, women treated by IVF are usually given extra progesterone after the embryo is transferred to the uterus. Recent data have shown that, in addition to progesterone administration, the production of progesterone by the patient's own ovary can be stimulated by treating the patients with a gonadotropin releasing hormone (GnRH) agonist. The aim of this study is to evaluate the effects of a GnRH agonist on IVF outcomes and blood progesterone levels in a group of women with a previous failure of the technique, associated with low blood progesterone levels.

Who can participate?
Women between 25 and 40 years of age with a previous IVF failure associated with low blood progesterone levels after embryo transfer

What does the study involve?
The study compares outcomes of two consecutive attempts of IVF in the same patients. Unlike the first attempt, in the second attempt the patients are treated with a GnRH agonist during 2 weeks after embryo transfer to the uterus. Except for this difference, the patients receive the same treatment in both attempts. Clinical pregnancy rate (number of pregnancies divided by the number of embryo transfer procedures) is measured from medical records at 3 months after embryo transfer.

What are the possible benefits and risks of participating?
Patients may have better IVF outcomes in the second attempt, without any additional side effects.

Where is the study run from?
MARGen Clinic (Spain)

When is the study starting and how long is it expected to run for?
September 2016 to April 2018

Who is funding the study?
MARGen Clinic (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1976

Study information

Scientific Title

Efficient treatment of luteal phase deficiency in HCG-triggered IVF cycles by prolonged administration of GnRH agonist after embryo transfer

Study objectives
This study aimed to identify women with IVF failure associated with low serum progesterone levels on the days following embryo transfer and to evaluate the effects of GnRH agonist on serum progesterone and pregnancy in GnRH antagonist-controlled and HCG-triggered IVF cycles.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not applicable

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

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
Luteal phase insufficiency in assisted reproduction

Interventions
In women who failed to get pregnant and had an abnormally low serum progesterone concentration after uterine transfer of embryos resulting from in vitro fertilisation, the protocol of the subsequent attempt was modified as follows. First, the treatment phase before embryo transfer, including ovarian stimulation, ovarian follicle puncture and oocyte recovery, in vitro fertilisation, and embryo in vitro culture and uterine transfer, were performed exactly as in the previous attempt. The only difference concerned the period after embryo transfer. In addition to direct progesterone administration, the patients were given daily subcutaneous injections of GnRH agonist (0.1 mg triptorelin) during 14 days following embryo transfer.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Triptorelin

Primary outcome measure
Clinical pregnancy rate (number of pregnancies divided by the number of embryo transfer procedures) is measured from medical records 3 months after embryo transfer

Secondary outcome measures
1. Implantation rate (number of gestational sacs containing a living embryo implanted in the uterus divided by the number of embryos transferred) is measured from medical records 6 weeks after embryo transfer
2. Serum progesterone concentration is measured using immunoassay at the 7th and 14th day after embryo transfer
3. Total dose of progesterone administered is measured from medical records at the 14th day after embryo transfer

Overall study start date
01/09/2016

Completion date
30/04/2018

Eligibility

Key inclusion criteria
1. Women
2. Aged between 28 and 39 years,
3. Failed to become pregnant
4. Had low luteal-phase progesterone levels in a previous in vitro fertilization attempt

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
25

Key exclusion criteria
1. Age of >40 years
2. Andrological gynecological and systemic pathologies unrelated to the corpus luteum function:
2.1. Azoospermia
2.2. Necrozoospermia
2.3. Uterine polyps and fibroids

2.4. Polycystic ovary syndrome
2.5. Endometriosis
2.6. Cushing syndrome
2.7. Diabetes
2.8. Hypothyreosis and hyperthyreosis
2.9. Body mass index >29

Date of first enrolment
01/09/2016

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Spain

Study participating centre
MARGen Clinic
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Sponsor information

Organisation
MARGen Clinic

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Sponsor type
Hospital/treatment centre

Website
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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
MARGen Clinic

Results and Publications

Publication and dissemination plan
Study results will be submitted to a specialized scientific journal during 2018.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date