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Early initiation of gonadotropin-releasing hormone (GnRH) antagonist during assisted reproductive technology (ART)

Submission date
03/08/2011

Recruitment status
No longer recruiting

Registration date
26/08/2011

Overall study status
Completed

Last Edited
14/02/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] 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 vitro fertilisation (IVF) is an assisted reproductive technology (ART) technique to help people with fertility problems to have a baby. Patients undergoing IVF receive various treatments to stimulate the release of multiple eggs from the ovaries. Sometimes a type of medication called gonadotropin-releasing hormone (GnRH) antagonists are used to prevent patients from releasing the eggs too early i.e., before the time of the egg pickup procedure. The GnRH antagonist is routinely given on day five of ovarian stimulation treatment, or can be administered before or after day five. One particular clinical condition in which the use of GnRH antagonists has been reported to be beneficial is in patients with polycystic ovarian syndrome (PCOS), where a sex hormone imbalance leads to the growth of benign masses on the ovaries. In these patients the use of GnRH antagonists reduced the incidence of severe ovarian hyperstimulation syndrome (OHSS), where too many eggs develop in the ovaries, making them very large and painful. The aim of this study is to compare two treatment schedules used in women with PCOS during IVF. Both treatment schedules are used in routine clinical practice. However, the choice between the two is based on the judgment of the treating physician because there are no studies that have looked at whether one schedule is better than the other.

Who can participate?
Women aged 18-40 with PCOS undergoing ART

What does the study involve?
Participants are randomly allocated into one of two groups. One group receives GnRH antagonist on day one, while the other group receives GnRH antagonist on day five of ovarian stimulation. The embryo implantation rate, pregnancy rate, delivery rate, miscarriage rate, and the incidence of severe OHSS are compared between the two groups.

What are the possible benefits and risks of participating?
There are no direct anticipated benefits from participating in the study. However, participation may help in the advancement of science by finding out which treatment schedule is superior to the other or to find out that the two schedules are similarly successful. There is no specific risk

of participating in the study. Both schedules have been used in clinical practice with success. There are other potential risks and complications associated with the clinical practice of ovarian stimulation and IVF. Such risks include, but are not limited to, the risk of anaesthetic, bleeding, which may require further surgery to control, infection, multiple pregnancy, higher incidence of miscarriage and ectopic pregnancy, and higher incidence of congenital malformation (birth defects) and chromosomal (genetic) abnormalities in babies born as a result of IVF. There is also a possible link between the use of fertility medication and ovarian cancer. Patients who use fertility medications are at increased risk of a condition called severe hyperstimulation syndrome, which could result in serious complications such as blood clot formation, kidney failure, fluid in the peritoneal cavity and around the lungs, and ovarian twisting, which would require surgery to correct.

Where is the study run from?
Hurley Medical Center (USA)

When is the study starting and how long is it expected to run for?
January 2006 to December 2009

Who is funding the study?
IVF Michigan, P.C. (USA)

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

195632-1

Study information

Scientific Title
Controlled ovarian hyperstimulation with long versus conventional protocol of gonadotropin-releasing hormone (GnRH) antagonist in women with polycystic ovarian disease (PCOD) undergoing assisted reproduction: a randomized controlled trial

Study objectives
The purpose of this study was to test the hypothesis that in women with polycystic ovarian syndrome (PCOS), early initiation of GnRH-ant. (day 1 of ovarian stimulation) is associated with higher implantation rate compared to conventional GnRH-antagonist protocol (starting on day 5 of ovarian stimulation).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board at Hurley Medical Center, 31/10/2006, ref: 195632-1

Study design
Single-center physician-blinded prospective randomized 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
Polycystic ovarian syndrome

Interventions
Controlled ovarian stimulation (COS) for intracytoplasmic sperm aspiration (ICSI) procedures in infertile patients with polycystic ovarian syndrome (PCOS). Two groups were studied.

The study group (group 1) received GnRH- antagonist subcutaneously (SC) starting on the same day on the beginning of COS using SC recombinant follicle stimulating hormone(r-FSH) 150-225 IU daily.

The control group (group 2) received GnRH- antagonist SC starting on treatment day 5 of SC r-FSH (150 -225 IU daily).

The implantation rate, clinical pregnancy rate, delivery rate, miscarriage rate, and the incidence of severe ovarian hyperstimulation syndrome between the two groups were compared.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Recombinant follicle stimulating hormone

Primary outcome measure
Implantation rates evaluated at the end of the study

Secondary outcome measures
1. Clinical pregnancy, delivery, and miscarriage rates
2. The incidence of severe ovarian hyperstimulation syndrome (OHSS)

Overall study start date
01/01/2006

Completion date
30/12/2009

Eligibility

Key inclusion criteria
1. Women (age between 18-40 years) with PCOS, undergoing assisted reproductive technology (ART). PCOS was defined according to Rotterdam criteria at least 2 of the following 3 features:
1.1. Oligo and/or anovulation
1.2. Clinical and/or biochemical signs of hyperandrogenism and
1.3. Polycystic ovary on ultrasound scan (The Rotterdam ESHRE/ASRM-sponsored PCOS consensus workshop group 2004)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
140

Key exclusion criteria
1. Hypothyroidism
2. Hyperprolactinemia
3. Non-classical form of congenital adrenal hyperplasia
4. Cushings syndrome
5. Androgen-secreting tumors

Date of first enrolment
01/01/2006

Date of final enrolment
30/12/2009

Locations

Countries of recruitment
United States of America

Study participating centre
Hurley Medical Center
Flint
United States of America
48503

Sponsor information

Organisation
Hurley Medical Center (USA)

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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/034npj057

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
IVF Michigan, P.C. (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration