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The efficacy of GnRH antagonists in cycles with mild ovarian hyperstimulation with recFSH in an intrauterine insemination program. A randomised placebo-controlled double-blinded investigator initiated study.

Submission date	Recruitment status	[_] Prospectively registered
09/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/01/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/08/2009	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR497

Study information

Scientific Title

Acronym
IUI study IMP 26162

Study objectives
We hypothesize that the use of a GnRH-antagonist in cycles with Mild Ovarian Hyperstimulation (MOH) combined with Intrauterine insemination (IUI) programs significantly improves live birth rates compared with MOH and a placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Intrauterine Insemination (IUI), Infertility, Subfertility

Interventions
The research group of patients will consist of two arms:
One group will receive ovarian stimulation with recFSH combined with placebo (the recFSH group).

One group will receive recFSH combined with a GnRH-antagonist (the recFSH-anta group). Both ovarian stimulation protocols will be followed by intrauterine insemination.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Live birth rate per couple

Secondary outcome measures
1. Total costs and cost-effectiveness
2. Ongoing (>12 weeks amenorrhoea) pregnancy rate per cycle commenced
3. Miscarriages (Preclinical miscarriage: spontaneous cessation of a biochemical pregnancy. Early miscarriage: any spontaneous abortion occurring after confirmation of clinical pregnancy and before completed 12 weeks of gestation. Late miscarriage: any spontaneous abortion occurring between completed 12 weeks of gestation and 16 completed weeks of gestation.) and ectopic pregnancies
4. Cumulative ongoing pregnancy rates per couple
5. Multiple births including the chorionicity
6. The occurrence of an LH surge or premature luteinization
7. Response of the ovaries to stimulation (number of follicles on day of Ovitrelle administration, speed of development, length of stimulation, quantities of medication used, etc.)

Overall study start date
15/11/2005

Completion date
14/11/2007

Eligibility

Key inclusion criteria
Primary and secondary subfertile patients between 18 and 35 years of age with a diagnosis of unexplained or mild male infertility will be included.
Definition of unexplained subfertility:
1. Normozoospermia using the guidelines of the WHO
2. Patent Fallopian tubes (both ovaries should be in situ)
3. Cycles varying between 24 and 35 days with an indication of ovulation
4. No abnormalities at laparoscopy and/or hysterosalpingography
Information from the post-coital test when performed will only be used for a prognostic model and not as an exclusion criterion.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Female

Target number of participants
520

Key exclusion criteria
1. Age of the woman <18 or >35 years
2. Duration of subfertility below 2 years
3. Manifest pathology of the Fallopian tubes
4. Severe forms of endometriosis (when laparoscopy has been performed: >AFS II)
5. An average total number of motile spermatozoa during semen analysis (performed twice in case of abnormal findings) below 10 million
6. Cycle disturbances (where otherwise ovulation induction would be used)
7. Previous IUI or IVF/ICSI treatment
8. If an initial ultrasound shows an image of a cyst that is larger than 25 mm treatment will be postponed for 1 month. Persistence of a cyst is a reason for exclusion.
9. Contraindications for recFSH (Gonal-F), rec-hCG (Ovitrelle) and Cetrotide

Date of first enrolment
15/11/2005

Date of final enrolment
14/11/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Isala Clinics Zwolle, location Sophia
Zwolle
Netherlands
8000 GK

Sponsor information

Organisation

Isala Clinics, Sophia (Isala Klinieken Locatie Sophia) (Netherlands)

Sponsor details
P.O. Box 10400
Zwolle
Netherlands
8000 GK

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/046a2wj10

Funder(s)

Funder type
Research council

Funder Name
Reproductive Medicine Research and Education Foundation (Stichting Onderzoek en Onderwijs Voortplantingsgeneeskunde Zwolle [SOOVZ]) (Netherlands)

Funder Name
Serono Benelux B.V. (Netherlands)

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