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Ovarian stimulation with follicle stimulating hormone (r-FSH) for women with high early follicular FSH and intra-uterine insemination (IUI) indication

Submission date 14/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/02/2006	**Overall study status** Completed	
Last Edited 26/08/2009	**Condition category** Urological and Genital Diseases	

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
NTR547; 03/203

Study information

Scientific Title

Study objectives
Hormonal stimulation with r-FSH during IUI treatment will result in multifollicular growth in subfertile women with elevated early follicular FSH values.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised open label active 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
Subfertility

Interventions
Couples will undergo a maximum of 6 IUI cycles.

Group 1: Three unstimulated IUI cycles, followed by three stimulated IUI cycles with r-FSH (follitropine). R-FSH will be given starting from day 3 of the cycle until one or more follicles reach 18 mm diameter, followed by hCG administration 10,000 IU and insemination. Dose will be increased in the next cycle until multifollicular growth occurs.

Group 2: Six stimulated IUI cycles. R-FSH will be given starting from day 3 of the cycle until one or more follicles reach 18 mm diameter, followed by hCG administration 10,000 IU and insemination. Dose will be increased in the next cycle until multifollicular growth occurs.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Multifollicular growth (on day of hCG administration, measured with ultrasound).

Secondary outcome measures
1. Pregnancy rate
2. FSH doses used
3. Cancellation rate
4. Side-effects of medication
5. Treatment load

Overall study start date
01/04/2004

Completion date
01/04/2008

Eligibility

Key inclusion criteria
1. Women with elevated early follicular FSH (cycle day 2-4)
2. Women between 18 and 45 years
3. Regular menstrual cycle between 25 and 35 days
4. Indication for IUI treatment
5. Normal hysterosalpingography
6. Normal serum Ca-125
7. Semen analyses: >2 million progressive motile spermatozoa
8. Ovulatory cycle

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
80

Key exclusion criteria

1. Untreated other endocrinal pathology
2. Abnormal vaginal blood loss of unknown origin
3. Contra-indications for use of r-FSH or human choronic gonadotropin (hCG)
4. Contra-indications for pregnancy
5. Congenital uterus anomaly
6. Endometriosis more than stage II (revised ASRM score)

Date of first enrolment
01/04/2004

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Center
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
VU University Medical Centre (VUMC) (Netherlands)

Sponsor details
Department of Obstetrics and Gynaecology,
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Research organisation

Funder Name
Gynaecological Research Foundation (Stichting Wetenschappelijk Onderzoek Gynaecologie [SWOG])

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