

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	<input type="checkbox"/> Prospectively registered
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/08/2009	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 chorionic 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,

Division of Reproductive Medicine

P.O. Box 7057

Amsterdam

Netherlands

1007 MB

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