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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

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

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
Multifollicular growth (on day of hCG administration, measured with ultrasound).

## Key secondary outcome(s))
1. Pregnancy rate
2. FSH doses used
3. Cancellation rate

4. Side-effects of medication
5. Treatment load

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Female

### 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)

**ROR**
https://ror.org/00q6h8f30

# Funder(s)

**Funder type**
Research organisation

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

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration