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Randomised controlled trial of bed rest versus no bed rest after intra-uterine insemination: impact on pregnancy rates

Submission date
27/06/2007

Recruitment status
No longer recruiting

Registration date
27/06/2007

Overall study status
Completed

Last Edited
02/11/2009

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
NTR426

Study information

Scientific Title

Study objectives
Does a short time of immobilisation (i.e., 15 minutes) after Intra-Uterine Insemination (IUI) have a potential advantage on pregnancy rates, compared to immediate mobilisation and does it outweigh the disadvantage of the extra time and working space it consumes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled parallel group multicentre 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
Intra uterine insemination will be performed in spontaneous cycles as well in cycles with Controlled Ovarian Hyper-stimulation (IUI-COH). IUI will be performed in lithotomy position with Trendelenburg tilt. After the insemination has been performed, the patient will, according to their allocation, immediately stand up and go home, or will return to normal supine position, and remain so for 15 minutes.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Ongoing pregnancy

Secondary outcome measures
Biochemical, clinical, ectopic pregnancy.

Overall study start date
01/09/2005

Completion date
01/09/2007

Eligibility

Key inclusion criteria
All patients, receiving IUI with fresh or cryo-preserved donor- or husbands sperm IUI with or without Controlled Ovarian Hyper-stimulation (IUI-COH), as a treatment for their subfertility will be eligible for the trial.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
280

Key exclusion criteria
1. Tubal pathology of both fallopian tubes
2. Patients younger than 18 years or older than 43 years of age

Date of first enrolment
01/09/2005

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
Center For Reproductive Medicine
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/10/2009		Yes	No