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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28782

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Alle patiënten die in de deelnemende ziekenhuizen een behandeling zullen ondergaan met intra uteriene inseminatie als therapie voor hun subfertiliteit komen in aanmerking voor de studie. Koppels komen in aanmerking voor behandeling met IUI indien de vrouw ovulatoir is met of zonder ovulatie inductie en minimaal één normaal doorgankelijke tuba heeft.

Sponsors and support

Primary sponsor: Prof. Dr. F. van der Veen
Academisch medisch centrum Amsterdam.
Centrum Voor Voortplantingsgeneeskunde

Intervention

Outcome measures

Primary outcome

Ongoing pregnancy.

Secondary outcome

Biochemical, clinical, ectopic pregnancy.

Study description

Background summary

Homologous and heterologous intra uterine insemination (IUI) is a commonly used treatment for couples with male, cervical and unexplained subfertility. The reported success rate of this therapy in terms of pregnancy and ongoing pregnancy, varies greatly, and is both dependent on the cause of subfertility as well as on the procedure that is used. Different variables in this IUI procedure have been well investigated. One of the issues that remains unresolved is the question whether after insemination the patient can immediately mobilize or should stay in supine position for a short period of time.
We designed a multicentre trial to answer the question if a short time of immobilization (i.e. 15 minutes) has a potential advantage on pregnancy rates after intra-uterine insemination, over immediate mobilization.
All patients, receiving IUI with fresh or cryo-preserved donor- or husband's sperm and IUI with or without controlled ovarian hyper stimulation (IUI-COH), as a treatment for their subfertility are eligible for the trial.
Follow up of each included patient will be until 3 cycles of IUI, or in case of pregnancy, until 12 weeks of gestation (ongoing pregnancy).
To answer the question whether bed rest is superior over immediate mobilisation after IUI, 185 couples are needed in each arm.

Study objective

Does a short time of immobilization (i.e. 15 minutes) after intra-uterine insemination have a potential advantage on pregnancy rates, compared to immediate mobilization and does it outweigh the disadvantage of the extra time and working space it consumes?

Study design

N/A

Intervention

Intra uterine insemination will be performed in spontaneous cycles as well in cycles with controlled ovarian hyperstimulation (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.

Contacts

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Eligibility criteria

Inclusion criteria

All patients, receiving IUI with fresh or cryo-preserved donor- or husband’s sperm
IUI with or without controlled ovarian hyper stimulation (IUI-COH), as a treatment for their subfertility will be eligible for the trial.

Exclusion criteria

1. Tubal pathology of both fallopian tubes;

2. Patients younger than 18 years or older than 43 years of age.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2005
Enrollment:	370
Type:	Actual

Ethics review

Positive opinion

Date:	14-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL386
NTR-old	NTR426
Other	: N/A
ISRCTN	ISRCTN53294431

Study results

Summary results
N/A