

Immobilisation or direct mobilisation after intrauterine insemination effects pregnancy rates? A randomised controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24490

Source

NTR

Brief title

IUI up or down

Health condition

subfertiliteit
subfertility

Sponsors and support

Primary sponsor: VU University Medical Center, Department of Obstetrics and Gynaecology
Source(s) of monetary or material Support: No funding required.

Intervention

Outcome measures

Primary outcome

Ongoing pregnancy rate per couple. Ongoing pregnancy is defined as an intrauterine pregnancy showing a normal developing foetus with positive heartbeat 10 weeks following IUI.

Secondary outcome

1. Ongoing pregnancy rate per cycle;
2. Pregnancy rate per couple and per cycle;
3. Cumulative pregnancy rate per couple;
4. Multiple gestation rate per ongoing pregnancy;
5. Miscarriage rate per couple.

Study description

Background summary

A single centre prospective randomized controlled trial to evaluate the effect of 15 minutes of immobilisation on IUI on the pregnancy rate in couples with unexplained, cervical factor or male subfertility at the VU University Medical Center, The Netherlands.

Study objective

To evaluate the effect of 15 minutes of immobilisation after IUI on pregnancy rate in couples with unexplained, cervical factor or male subfertility.

Study design

N/A

Intervention

15 minutes immobilisation after IUI or immediate mobilisation.

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

1. All couples with unexplained, cervical factor or male subfertility, with an indication for IUI;
2. All couples should have undergone an infertility work up including at least an hysterosalpingogram (HSG);
3. Unexplained subfertility will be diagnosed when ovulation is confirmed with a biphasic BTC and / or midluteal progesterone determination and HSG and / or laparoscopy have confirmed tubal patency at both sides;
4. In case of male factor the male partners should have semen analyses with a yield of > 2 million spermatozoa, but less than 10 million spermatozoa, after processing;
5. Subfertility due to cervical factor will be diagnosed when negative, well-timed postcoïtum tests are found.

Exclusion criteria

1. Cycles with a yield of < 2 x 10⁶ spermatozoa at time of insemination will be excluded from analysis;
2. Patients needing insemination with cryo-preserved semen or semen retrieved after flushing of the bladder will be excluded;
3. Patients with endocrine disorders like polycystic ovary syndrome or imminent ovarian failure (basal FSH > 12 IU IU/L) will be excluded as well.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2010
Enrollment:	500
Type:	Anticipated

Ethics review

Positive opinion	
Date:	20-07-2010
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	NL2313
NTR-old	NTR2418
Other	METc VUmc : 2010/090
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A