

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

Published: 22-07-2010

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To evaluate the effect of 15 minutes of immobilisation after IUI on the pregnancy rate

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual function and fertility disorders
Study type	Interventional

Summary

ID

NL-OMON34568

Source

ToetsingOnline

Brief title

IUI up or down

Condition

- Sexual function and fertility disorders

Synonym

infertility, intrauterine insemination

Research involving

Human

Sponsors and support

Primary sponsor: Voortplantingsgeneeskunde

Source(s) of monetary or material Support: Geen financiering nodig

Intervention

Keyword: immobilisation, IUI, mobilisation, pregnancy rate

Outcome measures

Primary outcome

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

Secondary outcome

Ongoing pregnancy rate per cycle

Pregnancy rate per couple per cycle

Cumulative pregnancy rate per couple

Multiple gestation rate per ongoing pregnancy

Miscarriage rate per couple

Study description

Background summary

Intrauterine insemination (IUI) is an established treatment for couples with unknown, mild male or cervical subfertility. It has been shown that several aspects are related to pregnancy rates, such as patient characteristics, sperm count, number of mature follicles, etcetera. However to date there is no consensus on whether immobilisation or direct mobilisation after the insemination has an effect on the pregnancy rate. Since approximately five years, our centre has changed from immobilisation for 10 minutes to direct mobilisation after IUI and no fall in pregnancy rate has been observed. Recently, two studies found that immobilisation after IUI did have a positive effect on the pregnancy rate but no clear explanation could be given for these results.

Study objective

To evaluate the effect of 15 minutes of immobilisation after IUI on the pregnancy rate

Study design

Prospective randomised controlled trial

Intervention

Patients will prospectively be randomised either to immediate mobilisation following IUI (group I) or to remain in a supine position for 15 minutes following IUI (group II).

Study burden and risks

All patients will receive the standard treatment for IUI, after the insemination one group will stay supine for 15 minutes while the other group will mobilise directly. There is no burden or risk associated with participation. No extra monitoring of either group is needed.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

All couples with unexplained, cervical factor or male subfertility, with an indication for IUI.

Exclusion criteria

less than 2 million spermatozoa at time of insemination

cryo-preserved semen

semen retrieved after flushing of the bladder

patients with endocrine disorders like polycystic ovary syndrome or imminent ovarian failure
(basal FSH > 12 IU IU/L)

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2010
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date: 22-07-2010

Application type: First submission

Review commission: METC Amsterdam UMC

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
CCMO	NL32266.029.10