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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28782

Bron
NTR

Verkorte titel
N/A

Aandoening

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.

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Ongoing pregnancy.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Tubal pathology of both fallopian tubes;

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2005
Aantal proefpersonen:	370
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A