

A study of the timing of intra-uterine insemination relative to ovulation.

Gepubliceerd: 15-10-2012 Laatste bijgewerkt: 15-05-2024

Early intra-uterine insemination (IUI; at the time of triggering of ovulation) may result in higher pregnancy rates as compared to late IUI (32-36 hours after triggering of ovulation), thereby decreasing the need for additional cycles of IUI and in...

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

Samenvatting

ID

NL-OMON23163

Bron

NTR

Aandoening

Subfertility.

Subfertiliteit / verminderde vruchtbaarheid.

Ondersteuning

Primaire sponsor: Maastricht University Medical Center +

Overige ondersteuning: Maastricht University Medical Center +

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter/endpoint is ongoing pregnancy rate, as defined as a pregnancy with fetal cardiac activity at ultrasound at 12 weeks of gestation, per IUI treatment strategy.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Intra-uterine insemination (IUI) combined with mild ovarian stimulation (MOS) and triggering of ovulation is a common treatment for subfertility, with pregnancy rates ranging between 7 and 12% per cycle. To couples who do not conceive after several cycles of IUI-MOS, In Vitro Fertilization (IVF) treatment is offered. The current practice in IUI-MOS is to administer human chorionic gonadotropin (hCG) for triggering ovulation when the largest follicle has reached a diameter of 16-18 mm, followed by IUI 32-36 hours later (i.e. around ovulation). However, studies on natural conception have proven that the maximum probability of pregnancy occurs with intercourse one day prior to ovulation. Therefore, it is hypothesized that IUI should be performed one day prior to ovulation (as triggered by hCG administration). Increasing the effectiveness of IUI-MOS would decrease the need for additional IUI-MOS cycles and IVF, and thereby would be cost-reducing.

Objective:

The main objective is to determine the effectiveness of IUI-MOS, comparing the ongoing pregnancy rate of a treatment strategy comprising a maximum of four cycles of IUI-MOS when performing IUI 32-36 hours after triggering of ovulation ("late IUI") with performing IUI at the time of triggering of ovulation ("early IUI"). The secondary objective is to determine (ongoing) pregnancy rate per cycle and per cause of subfertility, miscarriage rate, multiple pregnancy rate, live birth rate and adverse events. The tertiary objective is to determine the cost-effectiveness of both strategies and the potential cost-savings in view of a reduction of the need for additional IUI-MOS cycles and IVF treatment. Condition-specific questionnaires will be used to determine patient satisfaction (PCQ-Infertility) and quality of life (FertiQoL).

Study design:

Multi-center open-labelled randomised controlled trial.

Study population:

Couples with unexplained subfertility, mild male factor subfertility and cervical factor subfertility and who are eligible for IUI-MOS.

Intervention:

In group one, IUI will be performed 32-36 hours after triggering of ovulation by hCG, which is administered when the largest follicle has reached a diameter of 16-18 mm ("late IUI"). In group two, IUI will be performed at the time of triggering of ovulation by hCG, which is on the day the largest follicle has reached a diameter of 16-18 mm ("early IUI").

Main study parameters/endpoints:

The main study parameter/endpoint is the ongoing pregnancy rate per IUI-MOS treatment strategy.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Because only timing of IUI will be different in the two study groups, no burden or risks are involved. No extra blood samples or extra visits are needed. During each cycle, all couples are asked to fill in a questionnaire about factors potentially influencing pregnancy rate (e.g. weight, smoking, natural intercourse during treatment).

Doel van het onderzoek

Early intra-uterine insemination (IUI; at the time of triggering of ovulation) may result in higher pregnancy rates as compared to late IUI (32-36 hours after triggering of ovulation), thereby decreasing the need for additional cycles of IUI and in vitro fertilisation treatment.

Onderzoeksopzet

The primary outcome will be measured by ultrasound at 12 weeks of gestation in case of pregnancy (in case of non-pregnancy: At the end of the IUI treatment strategy).

The secondary outcomes will be measured in the same manner.

Onderzoeksproduct en/of interventie

In group one, IUI will be performed 32-36 hours after triggering of ovulation by human chorionic gonadotropin (hCG), which is administered when the largest follicle has reached a diameter of 16-18 mm ("late IUI").

In group two, IUI will be performed at the time of triggering of ovulation by hCG, which is on

the day the largest follicle has reached a diameter of 16-18 mm ("early IUI").

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Couples with unexplained subfertility, mild male factor subfertility and cervical factor subfertility who are eligible for IUI (estimated spontaneous pregnancy chance of <30% in the coming year, according to the prognostic model of Hunault) can be included. Only couples who are about to start IUI treatment, are eligible for this study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

In case of female age > 42 years old, female BMI > 35 kg/m², double-sided tubal pathology or severe male factor subfertility (< 1 million progressive motile sperm cells per sample in

repeated semen analyses), the couple is excluded. Couples who have already undergone at least one IUI-MOS cycle, are not eligible for this study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2013
Aantal proefpersonen:	358
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	15-10-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40074
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3486
NTR-old	NTR3666
CCMO	NL39738.068.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40074

Resultaten

Samenvatting resultaten

N/A