Intrauterine insemination for unexplained or mild male subfertility

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We hypothesize that 6 months of expectant management does not result in decreased ongoing pregnancy rates as 6 months of treatment with IUI-OH.

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

Samenvatting

ID

NL-OMON29303

Bron
Nationaal Trial Register

Verkorte titel
exIUI

Aandoening

Unexplained subfertility, onverklaarde subfertiliteit, intrauterine insemination, intra uteriene inseminatie, IUI, expectant management, expectatief

Ondersteuning

Primaire sponsor: AMC
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is ongoing pregnancy leading to a live birth occurring within 6 months after randomization. Live birth is defined as the birth of a live baby at 24 or more weeks of

gestation.

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND: Of the 20,000 couples who yearly seek fertility treatment, more than 50% are diagnosed with unexplained or mild male factor subfertility. In The Netherlands, the first line treatment for these women is intrauterine insemination with ovarian hyperstimulation (IUI-OH) if the probability of a natural conception within the following year is lower than 30% according
to the validated model of Hunault. An estimated 28,500 cycles are conducted every year in the Netherlands, costing approximately 20 million euros, without any evidence that IUI-OH increases live birth rate compared to expectant management. Besides the costs, IUI-OH bears a risk of multiple pregnancies. Women with a multiple pregnancy have an increased risk of premature birth, with associated neonatal mortality and morbidity.

THE PRIMARY OBJECTIVE: To evaluate whether expectant management for 6 months does not lead to a decrease in ongoing pregnancy rate leading to a live birth compared to 6 months IUI-OH.

HYPOTHESIS: We hypothesize that 6 months of expectant management does not result in decreased ongoing pregnancy rates compared to 6 months of treatment with IUI-OH.

STUDY DESIGN: randomized multicentre, non-inferiority trial with cost-effectiveness analysis.

STUDY POPULATION Couples diagnosed with unexplained or mild male subfertility according to the Dutch guideline and an unfavourable prognosis for natural onception.

INTERVENTION: 6 months expectant management.

STANDARD INTERVENTION TO BE COMPARED: 6 months IUI-OH .

OUTCOME MEASURES: Ongoing pregnancies leading to a live birth conceived within 6 months after randomisation

SAMPLE SIZE: We expect a 30% live birth rate after 6 months IUI-COH. To evaluate whether 6 months expectant management does not result in a decrease of an ongoing pregnancy rate of 7%, we need 982 patients. (power 80%, alpha error 0.05). Anticipating 10% lost to follow up, we need to randomise 1,091 women.

Doel van het onderzoek

We hypothesize that 6 months of expectant management does not result in decreased ongoing pregnancy rates as 6 months of treatment with IUI-OH.

Onderzoeksopzet

6 months

Onderzoeksproduct en/of interventie

Expectant management (experimental arm) vs intra uterine insemination with ovarian hyperstimulation (control arm)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

12 months unprotected intercourse without conception, female age between 18 and 42 years, a regular ovulatory cycle and at least one patent fallopian tube. The male partner has no or a mild impairment of semen quality with a total motile sperm count (TMSC or VCM) above 3 million. Obtained written informed consent. A 12-month prognosis for natural conception (calculated according to the model of Hunault) of 30% or less, or a 12-month prognosis of more than 30% and returning after 6 months of expectant management without conception.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

IUI-OH with sperm donation, couples with a medical contra indication for pregnancy, couples with previous ART in the current treatment episode

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2016
Aantal proefpersonen:	1091
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	18-12-2015
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	NL5455
NTR-old	NTR5599
Ander register	AMC : 80-83700-98-16505

Resultaten