Intrauterine insemination for unexplained or mild male subfertility

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29303

Source
Nationaal Trial Register

Brief title
exIUI

Health condition

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

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcomes are number of incomplete/cancelled cycles, clinical pregnancy (defined as the presence of a gestational sac at 5-7 weeks after IUI) ongoing pregnancy, (defined as a the presence of a positive heartbeat at 10 weeks after IUI), multiple pregnancy (defined as two or more gestational sacs at 5-7 weeks after IUI), ongoing multiple pregnancy (defined as the presence of two or more heart beats at 10 weeks after IUI), miscarriage (defined as the loss of a pregnancy prior to 16 weeks gestation), ectopic pregnancy (defined as the ectopic nidation of a pregnancy), time to ongoing pregnancy, pregnancy outcomes (such as birth weight and premature birth or pre-eclampsia), couples preference, quality of life and financial costs.

Study description

Background summary

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.

Study objective

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

Study design

6 months

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2016
Enrollment:	1091
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	18-12-2015
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	NL5455
NTR-old	NTR5599
Other	AMC : 80-83700-98-16505

Study results