

Intrauterine insemination for unexplained or mild male subfertility

Published: 11-10-2016

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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...

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

Summary

ID

NL-OMON50720

Source

ToetsingOnline

Brief title

The EX IUI study

Condition

- Sexual function and fertility disorders

Synonym

unexplained subfertility and mild male subfertility

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W, ZonMw

Intervention

Keyword: expectant management, IUI, mild male subfertility, unexplained subfertility

Outcome measures

Primary outcome

Ongoing pregnancy, conceived within a time horizon of 6 months after randomisation leading to live birth. Live Birth is defined as the birth of a baby at 24 or more weeks gestation.

Secondary outcome

- * IUI outcome parameters, such as the total number of follicles, incomplete/cancelled cycles.
- * Clinical pregnancy; defined as the presence of a gestational sac seen by transvaginal sonography 5-7 weeks after IUI.
- * Ongoing pregnancy; defined as the presence of positive heart beat as seen by transvaginal sonography 10 weeks after IUI.
- * Multiple pregnancy; defined as two or more gestational sacs seen by transvaginal sonography 5-7 weeks after IUI
- * Ongoing multiple pregnancy; defined as two or more positive heart beats seen by transvaginal sonography 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, confirmed with sonography or laparoscopy
- * Time to ongoing pregnancy
- * Pregnancy outcomes such as birth weight and premature birth or pre-eclampsia will be noted.

* Couples* preference, measured by means of a questionnaire (100 patients)

* Generic quality of life measured by questionnaires (SF36, fertiQoL and HADS),

women in the expectant arm will be ask to keep a diary.

* Financial Costs

Study description

Background summary

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.

Study 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.

Intervention

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

Study burden and risks

As we compare strategies that are already in current practice, no additional risks or burdens are expected from the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- At least 12 month unprotected regular intercourse or self insemination without conception
- Regular ovulatory cycle
- At least one sided tubal patency, established according to local protocol
- Total motile sperm count (TMSC or VCM) above 3 million.

- An unfavourable prognosis for natural conception, defined as:
women of 18 years until 38 years with a prognosis < 30% (model of Hunault) or;
women of 38 years until 42 years or;
women of 18 years until 38 years with an initial favourable prognosis (>30 %
Hunault model) and returning after 6 months expectant management without
conception.
- Obtained written informed consent.

Exclusion criteria

- ART in the current treatment episode
- IUI-OH with sperm bank donation
- Couples with a medical contra indication for pregnancy
- Couples with sexual problems interfering with the occurrence of a natural
conception pregnancy.

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):	26-01-2017
Enrollment:	1091
Type:	Actual

Ethics review

Approved WMO	
Date:	11-10-2016

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2017

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	06-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	27-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	18-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	25-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	19-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	31-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	10-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	31-07-2020

Application type: Amendment
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	NL57383.018.16