# Effectiveness of intrauterine insemination with ovarian hyperstimulation in couples with an unexplained moderately reduced fertility

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
20/12/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
20/12/2005	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
19/10/2007	Pregnancy and Childbirth			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Mrs P Steures

#### Contact details

Academic Medical Center
Center of Reproductive Medicine
OFO-project, H4-213
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 566 3857
ofoproject@amc.uva.nl

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

# Study information

#### Scientific Title

## **Study objectives**

There is no additional benefit of Intrauterine Insemination (IUI) with Controlled Ovarian Hyperstimulation (COH) over expectant management for 6 months in couples with unexplained subfertility and a chance of a spontaneous pregnancy between 30% and 40%. Categorisation of unexplained subfertile couples by their prognosis can identify those couples who benefit from IUI with COH and those who do not.

## Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the local medical ethics committee

## Study design

Multicentre, randomised, active controlled, parallel group trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

Treatment

#### Participant information sheet

## Health condition(s) or problem(s) studied

**Unexplained Subfertility** 

#### Interventions

After informed consent had been given, couples were randomly allocated between IUI with COH and expectant management for six months.

Couples allocated to IUI with COH started treatment in the next cycle. Controlled ovarian hyper stimulation as well as semen preparation and insemination regimens were performed according to hospital-specific protocols.

Couples allocated to expectant management were followed until an ongoing pregnancy occurred within six months, these pregnancies were finally followed until birth. If no pregnancy occurred, follow-up ended after this period. If a pregnancy miscarried, follow-up continued until the next pregnancy or the end of the six months period.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

The primary endpoint was ongoing pregnancy within six months. Ongoing pregnancy was defined as the presence of foetal cardiac activity at transvaginal sonography at a gestational age of at least 12 weeks.

## Secondary outcome measures

Secondary endpoints were total number of clinical pregnancies, miscarriages and multiple pregnancies.

### Overall study start date

01/06/2002

# Completion date

01/07/2005

# **Eligibility**

# Key inclusion criteria

All subfertile couples in whom no reason is found during the basic fertility work-up for their subfertility and in whom their spontaneous pregnancy chance in the next year, calculated by the results of the basic fertility work-up, is between 30% and 40%.

# Participant type(s)

Patient

# Age group

Adult

#### Sex

Female

# Target number of participants

250

# Key exclusion criteria

All couples in whom a reason is found for their subfertility or who are having another prognosis calculated

# Date of first enrolment

01/06/2002

# Date of final enrolment

01/07/2005

# Locations

#### Countries of recruitment

Netherlands

# Study participating centre Academic Medical Center

Amsterdam Netherlands 1100 DD

# Sponsor information

# Organisation

Academic Medical Centre (AMC) (Netherlands)

# Sponsor details

Meibergdreef 9 Amsterdam Netherlands 1105 AZ

## Sponsor type

University/education

#### Website

http://www.amc.uva.nl/

#### **ROR**

https://ror.org/03t4gr691

# Funder(s)

# Funder type

Research organisation

#### Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	15/07/2006		Yes	No