

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

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/10/2007	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

Protocol serial number
1

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

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