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

No registrations found.

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

Summary

ID

NL-OMON25051

Source
NTR

Brief title
subfertility

Health condition

Unexplained subfertility.

Sponsors and support

Primary sponsor: OFO-project
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Source(s) of monetary or material Support: This study was facilitated by grant 94512002 from ZonMW, The Netherlands Organization for Health Research and

Development, The Hague, The Netherlands.

Intervention

Outcome measures

Primary outcome

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

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

Study description

Background summary

Objectives:

To investigate the effectiveness of intrauterine insemination (IUI) with controlled ovarian hyperstimulation (COH) in couples with unexplained subfertility and a specific prognostic profile for their chance on a spontaneous pregnancy, and to study whether categorization of unexplained subfertile couples by their prognosis can identify those couples who benefit from IUI with COH and those who do not.

Design:

Randomised controlled trial.

Setting:

27 fertility centres in The Netherlands.

Participants:

Subfertile couples with unexplained subfertility and a prognosis of a spontaneous ongoing pregnancy within 12 months between 30 and 40%.

Interventions:

Couples were randomly allocated to IUI with COH for six months or expectant management for six months.

Main outcome measures:

Ongoing pregnancy within 6 months, resulting in the live birth of at least one child.

Results:

We randomised 254 couples, 127 couples were allocated to IUI with COH and 127 couples were allocated to expectant management. In the IUI with COH group, 31 couples (30%) conceived, of which 23 resulted in live birth (22%). In the expectant management group, 26 couples (28%) conceived, of which 22 resulted in live birth (23%). (Relative risk 0.95 95% CI 0.69 to 1.3). The number of multiple pregnancies in both groups was xx.

Conclusions:

A substantial beneficial effect of IUI with COH in couples with unexplained subfertility and an intermediate prognosis can be excluded. Expectant management of six months is justified in these couples. Classification into prognostic categories might prevent unnecessary treatment.

Study objective

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 on a spontaneous pregnancy between 30% and 40%.Categorization of unexplained subfertile couples by their prognosis can identify those

couples who benefit from IUI with COH and those who do not.

Study design

N/A

Intervention

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 hyperstimulation as well as semen preparation and insemination regimens were performed according to hospital-specific protocols.
Couples allocated to expectant management were followed till 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.

Contacts

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Eligibility criteria

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%.

Exclusion criteria

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

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):	01-06-2002
Enrollment:	250
Type:	Actual

Ethics review

Positive opinion

Date:	08-09-2005
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	NL155
NTR-old	NTR190
Other	: 1
ISRCTN	ISRCTN72675518

Study results

Summary results
Lancet. 2006 Jul 15;368(9531):216-21.

Ned Tijdschr Geneeskd. 2008 Jul 5;152(27):1525-31.

Partly presented in a poster presentation at the 21st Annual Meeting of the European Society of Human Reproduction and Embryology, Copenhagen, 2005.

Will be presented in an oral presentation at the Gynaecongres of november 2005.
