

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25051

Bron

NTR

Verkorte titel

subfertility

Aandoening

Unexplained subfertility.

Ondersteuning

Primaire sponsor: OFO-project

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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%.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2002
Aantal proefpersonen:	250
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	08-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL155
NTR-old	NTR190
Ander register	: 1
ISRCTN	ISRCTN72675518

Resultaten

Samenvatting resultaten

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

Ned Tijdschr Geneesk. 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.
