The effectiveness of intrauterine insemination in subfertile couples with an isolated cervical factor: a randomised controlled trial.

No registrations found.

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

Summary

ID

NL-OMON26297

Source
Nationaal Trial Register

Brief title
subfertility, cervical factor, IUI

Health condition

subfertility

Sponsors and support

Primary sponsor: OFO-project
t.a.v. B.W. Mol
Academic Medical Center
Center of Reporductive medicine, H4-213
Postbus 22660
1100 DD Amsterdam
Phone: 0031205663857
Fax: 0031206963489
e-mail: ofoproject@amc.uva.nl or b.mol1@chello.nl
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 assess the effectiveness of intrauterine insemination (IUI) in subfertile couples with a cervical factor. The effectiveness of IUI is well established for male and unexplained subfertility. Data on IUI for cervical factor subfertility from five small trials are conflicting.

Design:

Randomised controlled trial.

Setting:

17 fertility centres in The Netherlands.

Participants:

Subfertile couples with a cervical factor, diagnosed by a well-timed, non-progressive post-coital test (PCT) with normal semen parameters and otherwise no factors that reduced fertility.

Interventions:

Couples were randomly allocated to IUI for six months or expectant management for six months. In the first three IUI cycles no controlled ovarian hyperstimulation (COH) was given. If these attempts failed subsequent IUI cycles were performed with COH.

Main outcome measures:

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

Results:

We randomised 101 couples, xx couples were allocated to IUI and xx couples were allocated to expectant management. In the IUI group, xx couples (xx%) conceived, of which xx resulted in live birth (xx%). In the expectant management group, xx couples (xx%) conceived, of which xx resulted in live birth (xx%). (Relative risk 1.5 95% CI 0.99 to 2.2). The number of multiple pregnancies in both groups was xx.

Conclusions:

This trial suggest a beneficial effect of IUI in couples with an isolated cervical factor. This effect should be considered by those who plea against performance of the post-coital test.

Study objective

We hypothesized a beneficial effect of IUI in couples with an isolated cervical factor. Furthermore we hypothesized that the post-coital test can identify those couples who would benefit from IUI without ovarian hyperstimulation.

Study design

N/A

Intervention

Couples were randomly allocated to IUI for six months or expectant management for six months. In the first three IUI cycles no controlled ovarian hyperstimulation (COH) was given. If these attempts failed subsequent IUI cycles were performed with COH. Couples allocated to expectant management were followed till an ongoing pregnancy occurred within six months. 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

Public
Academic Medical Center (AMC), Center of Reproductive medicine, OFO-project, H4-213, P.O. Box 22660
P. Steures
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663857
Scientific
Academic Medical Center (AMC), Center of Reproductive medicine, OFO-project, H4-213, P.O. Box 22660
P. Steures
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663857

Eligibility criteria

Inclusion criteria

Couples with a cervical factor and otherwise no factors that reduced their fertility, i.e. a prognosis for a treatment independent ongoing pregnancy in the next year higher than 30%. A cervical factor was diagnosed by a well-timed, non-progressive post-coital test (PCT) with normal semen parameters.

Exclusion criteria

All other subfertile couples.

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:	100
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
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	NL167
NTR-old	NTR203
Other	: 2
ISRCTN	ISRCTN63217062

Study results

Summary results
Fertil Steril. 2007 Dec;88(6):1692-6. Epub 2007 May 7.

Partly presented in an oral presentation at the Conjoint Annual Meeting of the American Societty for Reproductive Medicine and the Canadian Fertility and Andrology Society, ASRM/CFAS 2005, Montreal, Quebec, Canada.
