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

Submission date
08/02/2006

Recruitment status
No longer recruiting

Registration date
08/02/2006

Overall study status
Completed

Last Edited
19/10/2007

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2

Study information

Scientific Title

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

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
Subfertility

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.

Couples allocated to expectant management were followed until 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.

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
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.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
All other subfertile couples

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 Center Amsterdam (The Netherlands)

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	01/12/2007		Yes	No