

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

☐ Prospectively registered

☐ Protocol

Registration date
08/02/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
19/10/2007

Condition category
Pregnancy and Childbirth

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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 measures

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

Overall study start date

01/06/2002

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

Age group

Adult

Sex

Female

Target number of participants

100

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)

Sponsor details

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

Sponsor type

University/education

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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