

A randomised clinical trial assessing the additional value of ovarian hyperstimulation in intrauterine insemination (IUI) for couples with an abnormal post-coital test (PCT)

Submission date 08/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/07/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

3

Study information

Scientific Title

A randomised clinical trial assessing the additional value of ovarian hyperstimulation in intrauterine insemination (IUI) for couples with an abnormal post-coital test (PCT)

Study objectives

We hypothesised that controlled ovarian hyperstimulation (COH) is of additional value to IUI in couples with a cervical factor and a poor prognosis, i.e. less than 30% spontaneous pregnancy chance in the next year.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Multicentre, randomised, active controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Subfertility

Interventions

These couples were randomly allocated to three cycles of IUI with COH or three cycles of IUI without COH. Controlled ovarian hyperstimulation as well as ovulation detection induction, semen preparation and insemination regimens were performed according to hospital-specific protocols.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The primary endpoint was ongoing pregnancy within three cycles of IUI. 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 were eligible if they had an abnormal PCT, either due to cervical hostility diagnosed by a well-timed, non-progressive PCT with normal semen parameters or due to a poor semen quality. The spontaneous pregnancy chance in the next year, leaving the result of the PCT out of consideration, was less than 30%.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

265

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

ZonMw

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

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		01/12/2007	15/07/2021	Yes	No