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

Recruitment status No longer recruiting	Prospectively registered		
	☐ Protocol		
Overall study status Completed	Statistical analysis plan		
	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting Overall study status Completed		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

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.

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 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

Age group

Adult

Sex

Female

Target number of participants

250

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)

Sponsor details

Meibergdreef 9 Amsterdam Netherlands 1105 AZ

Sponsor type

University/education

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

LocationNetherlands

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