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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

Registration date
08/02/2006

Overall study status
Completed

Last Edited
15/07/2021

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

Contact name
Mrs P Steures

Contact details
Academic Medical Center
Center of Reproductive Medicine
OFO-project
H4-213
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5663857
ofoproject@amc.uva.nl

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

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