ISRCTN35766970 https://doi.org/10.1186/ISRCTN35766970

Novel approaches in in-vitro fertilisation (IVF)

Submission date 08/03/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/03/2006	**Overall study status** Completed	
Last Edited 27/10/2022	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Esther Heijnen

Contact details
Department of Reproductive Medicine
University Medical Center Utrecht
Heidelberglaan 100
Utrecht
Netherlands
3584 CX
-
esther.heijnen@organon.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR587

Study information

Scientific Title
Novel approaches in in-vitro fertilisation (IVF)

Study objectives
Strategies involving shorter and milder ovarian stimulation protocols and single embryo transfer may allow for more in-vitro fertilisation (IVF) cycles in the same period of time, resulting in similar term live birth rate per treatment period despite a minor reduction in birth rate per treatment cycle.

Ethics approval required
Old ethics approval format

Ethics approval(s)
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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Infertility

Interventions
Patients were randomly assigned to undergo either:
1. Mild treatment (mild ovarian stimulation with gonadotropin-releasing hormone [GnRH] antagonist co-treatment combined with single embryo transfer), or
2. Standard treatment (stimulation with a GnRH agonist long-protocol and transfer of two embryos)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Gonadotropin-releasing hormone (GnRH)

Primary outcome measure
The primary outcome parameters chosen for this study were:
1. Pregnancy within one year of treatment after randomisation leading to term (greater than 37 weeks gestation) live birth
2. Total costs per couple and child up to six weeks after expected delivery
3. Patient discomfort/distress during IVF treatment

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/02/2002

Completion date
01/03/2005

Eligibility

Key inclusion criteria
1. Patients with an indication for IVF or IVF/intracytoplasmic sperm injection (ICSI) based on tubal, male or unexplained infertility were recruited
2. Patients less than 38 years with a normal menstrual cycle (cycle length between period 25 - 35 days) and without severe obesity or underweight (body mass index [BMI] 18 - 28 kg/m^2) were eligible for the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
400

Total final enrolment
404

Key exclusion criteria
Does not comply with the above inclusion criteria.

Date of first enrolment
01/02/2002

Date of final enrolment

01/03/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Reproductive Medicine
Utrecht
Netherlands
3584 CX

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

Sponsor details
Department of Reproductive Medicine
Heidelberglaan 100
Utrecht
Netherlands
3584 CX

Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

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
Not provided at time of registration

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		03/03/2007		Yes	No
Other publications	Psychological impact	01/09/2007		Yes	No
Results article	Patient discomfort, risks and costs	05/04/2008	27/10/2022	Yes	No