ISRCTN10841210 https://doi.org/10.1186/ISRCTN10841210

Does the addition of Recombinant Luteinising Hormone (recLH) (Luveris) to a regimen of Recombinant Follicle Stimulating Hormone (recFSH) (Gonal-F) and Gonadotropin Releasing Hormone (GnRH) antagonist (Cetrotide) improve ovarian response and implantation rates in patients age >35 years undergoing in vitro fertilisation (IVF)/embryo transfer (ET)?

Submission date
14/02/2006

Registration date
14/02/2006

Last Edited
10/06/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Urological and Genital Diseases

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR546; 03/159

Study information

Scientific Title

Acronym
Luveris study

Study objectives
The hypothesis of this study is that the addition of recLH (Luveris) to a protocol of recFSH (Gonal-F) and GnRH antagonist (Cetrotide) will improve the pregnancy rates in women over the age of 35 years undergoing IVF/ET.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre randomised open label 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
Subfertility

Interventions
Patients will receive a standard protocol of Gonal-F (follitropine; 225 IU/day) from cycle day 2-4 and Cetrotide (Cetrorelix; 0.25 mg/day) from day 6 of stimulation. They will be randomized on day 6 of stimulation to receive either Gonal-F and Luveris (150 IU/day) or continue with Gonal-F alone. In both cases, the dose of Gonal-F will remain unchanged. As in our standard treatment protocol, human choronic gonadotropin (hCG) (Pregnyl) will be given when at least 3 follicles reach 16 mm and ovum collection, embryo replacement and luteal support with vaginal progesterone will all be applied as in our routine IVF procedures.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Pregnancy rate/embryo transfer
2. Implantation rate (hCG measurement 15 days after ovum pick up)

Secondary outcome measures
1. Number of follicles >15 mm on day hCG
2. Number of ova collected

Overall study start date
01/01/2006

Completion date
01/01/2010

Eligibility

Key inclusion criteria
Age >35 years undergoing IVF or intracytoplasmic sperm injection (ICSI) for any indication

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
600

Key exclusion criteria
Women with polycystic ovary syndrome (PCOS)

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Center
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
VU University Medical Centre (VUMC) (Netherlands)

Sponsor details
Department of Obstetrics and Gynaecology,
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Research organisation

Funder Name
Gynaecology Research Foundation (Stichting Wetenschappelijk Onderzoek Gynaecologie [SWOG])

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	01/10/2013		Yes	No