

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

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

14/02/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

10/06/2014

Condition category

Urological and Genital Diseases

☐ Individual participant data

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

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 chorionic 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,

Division of Reproductive Medicine

P.O. Box 7057

Amsterdam

Netherlands

1007 MB

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