

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

Prof R. Homburg

Contact details

VU University Medical Center
Department of Obstetrics and Gynaecology
Division of Reproductive Medicine
P.O. Box 7057
Amsterdam
Netherlands

1007 MB
+31 (0)20 4440070
R.homburg@vumc.nl

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Research organisation

Funder Name

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

Results and Publications

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