ISRCTN98623456 https://doi.org/10.1186/ISRCTN98623456

Comparison study of Puregon® and Elonva® used in a long gonadotropin-releasing hormone (GnRH) agonist protocol for IVF stimulation

Submission date
20/02/2012

Recruitment status
Stopped

Registration date
27/03/2012

Overall study status
Stopped

Last Edited
21/01/2019

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In vitro fertilisation (IVF) is one of several techniques available to help people with fertility problems to have a baby. Gonadotrophins are medicines used in IVF to stimulate ovulation (the monthly release of an egg). Elonva is a new, long acting gonadotropin. As Elonva is a long acting gonadotropin, only one injection is needed instead of one injection every day, but the dosage cannot be adapted as with daily injections. The aim of this study is to compare Elonva with another gonadotropin that is routinely used in IVF (Puregon).

Who can participate?
Women younger than 40 undergoing a second IVF cycle

What does the study involve?
Participants are randomly allocated to be treated with either Elonva or Puregon. The pregnancy rate, number of eggs retrieved, doses of gonadotropins used and days of stimulation needed are compared between the two groups.

What are the possible benefits and risks of participating?
A possible benefit of participating in this study is patient comfort because they will only need one injection instead of daily injections with Puregon. A possible risk is a different pregnancy rate or number of eggs although previous studies do not show this.

Where is the study run from?
1. H. Hart hospital, Leuven, Belgium
2. ZOL (ziekenhuis post-Limburg), Genk, Belgium

When is the study starting and how long is it expected to run for?
March 2012 to April 2013

Who is funding the study?
Leuven Institute for Fertility and Embryology (Belgium)

Who is the main contact?
Dr Stephan Gordts

Contact information

Type(s)
Scientific

Contact name
Dr Stephan Gordts

Contact details
Leuven Institute for Fertility and Embryology
Tiensevest 168
Leuven
Belgium
3000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised controlled trial comparing Puregon® and Elonva® both in a GnRH agonist protocol for IVF stimulation

Study objectives
Elonva® is a long acting gonatropin that can be used for IVF stimulation. If similar pregnancy and live birth rates can be achieved, this could give more comfort for the patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Female infertility

Interventions
Both groups: Decapeptyl® SR, between day 21 and day 25 of the cycle. Ultrasound control after 2 weeks.

Group 1: Start of Puregon® on day of scan. Ultrasound and blood test after 5 days of stimulation with option of adapting the dosage.
Group 2: Injection of Elonva® on day of scan. Ultrasound and blood test on day 8 with evaluation of further stimulation is needed.

For both groups: As soon as follicles on scan are larger than 17 mm, Pregnyl® will be given and oocyte pick-up will be planned 35 hours after injection of Pregnyl®. Embryo transfer will be performed according to the Belgian legislation.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Decapeptyl®, Elonva®, Pregnyl®, Puregon®

Primary outcome measure
Pregnancy rate

Secondary outcome measures
1. Days of stimulation needed
2. Doses of gonadotropins used
3. Number of oocytes retrieved
4. Fertilization rate
5. Number of embryos for cryopreservation

Overall study start date

01/03/2012

Completion date
01/04/2013

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Second IVF attempt
2. Younger than 40 years
3. Anti-mullerian hormone less than 3

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
160

Key exclusion criteria
1. Previous cycle ovarian hyper stimulation syndrome
2. Pre-implantation genetic diagnosis cycles
3. IVF cycles using testicular sperm biopsy
4. Patients needing more than 2500 U of gonadotropins in the first cycle
5. Patients above 40 years

Date of first enrolment
01/03/2012

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
Belgium

Study participating centre
Leuven Institute for Fertility and Embryology
Leuven

Belgium
3000

Sponsor information

Organisation
Leuven Institute for Fertility and Embryology [LIFE] (Belgium)

Sponsor details
Tiensevest 168
Leuven
Belgium
3000

Sponsor type
Hospital/treatment centre

Website
http://www.lifeleuven.be/

ROR
https://ror.org/012rp6f89

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leuven Institute for Fertility and Embryology [LIFE] (Belgium)

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