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# 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