

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	<input type="checkbox"/> Prospectively registered
Registration date 27/03/2012	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 21/01/2019	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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Belgium
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Additional identifiers

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

Study type(s)
Treatment

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(s)

Pregnancy rate

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration