

Poor Responders Intervention Trial

PARTICIPANT INFORMATION SHEET

You are being invited to take part in a research study. Before you make your decision, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. You may want to talk to others about the study before taking part.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1

What is the purpose of the study?

There are three commonly used regimens used to suppress the pituitary hormones during In Vitro Fertilisation (IVF). The purpose of this research is to find out which of these is the most effective for women who have shown a poor response in their previous treatment cycle(s). There is currently no evidence to say which gives the best outcome.

It is necessary during IVF treatment to control the reproductive cycle. In order to do this drugs are used to suppress the reproductive hormones released by the pituitary gland in the brain. These hormones are the Follicle Stimulating Hormone (FSH) and the Luteinising Hormone (LH). Both these hormones are stimulated by the Gonadotrophin Releasing Hormone (GnRH).

There are two types of drugs which suppress the pituitary hormones. The first is a GnRH agonist, called Nafarelin. An agonist is a drug which mimics the action of a naturally occurring substance in the body. Nafarelin activates the pituitary just like the GnRH in the body, but while the GnRH triggers the release of hormones by repeated on/off pulses, Nafarelin in IVF treatment delivers a long, sustained burst which keeps the pituitary in the 'off' mode.

The second drug is a GnRH antagonist, called Cetrorelix. An antagonist is a drug which opposes the action of a naturally occurring substance in the body. In this way, Cetrorelix prevents the release of pituitary hormones.

There are three different regimes used to block the release of the reproductive hormones. They are as follows:

1. The GnRH agonist (Nafarelin) long regimen

- Day 21 of menstrual cycle: start Nafarelin nasal spray (continued until HCG injection)
 - ↓ approx 2 weeks later
 - Ovarian stimulation with FSH injections (continued until HCG injection)
 - ↓ approx 9-14 days later
 - HCG injection (to mature the eggs)
 - ↓ 36 hours later
 - Egg collection *
- ↓ 2, 3, or 5 days later
- Embryos put back into the womb
 - ↓ 2 weeks later
- Pregnancy test
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- *Starting on the day of egg collection, you will take a daily dose of Progesterone (to prepare the lining of the womb), which is taken in the form of pessaries inserted into the vagina. These should be taken daily up until the pregnancy test. If the test is positive, the pessaries should be continued until the 8th week of pregnancy.
- *The approximate duration of this treatment regimen (from the start of Nafarelin until the pregnancy test is performed) is 6 weeks.*

2. The GnRH agonist (Nafarelin) short regimen

- Day 2/3 of menstrual cycle: Start Nafarelin nasal spray (continued until HCG injection)
 - Day 3/4: Ovarian stimulation with FSH injections (continued until HCG injection)
 - ↓ approx 9-14 days later
 - HCG injection (to mature the eggs)
 - ↓ 36 hours later
 - Egg collection *
- ↓ 2, 3, or 5 days later
- Embryos put back into the womb