



Participant Information Sheet

Study Title: **The FIIX Study.** The **F**ertility and **I**VF (IVF) and **I**ntra Uterine Insemination (IUI) trial in couples with un**X**plained infertility

You are invited to take part in The FIIX Study

Lead Investigators: Professor Cindy Farquhar, Dr Lucy Prentice, and Dr Lynn Sadler

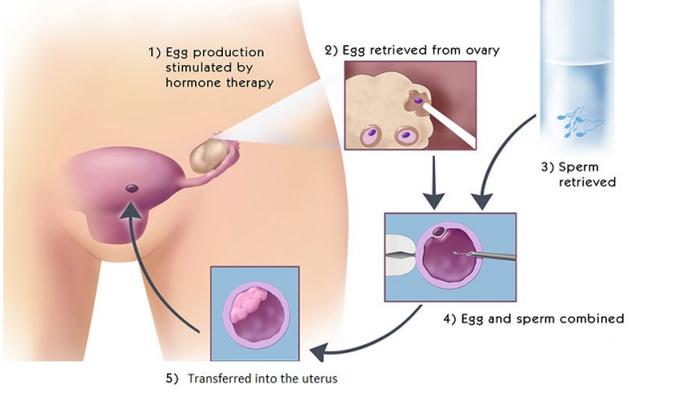
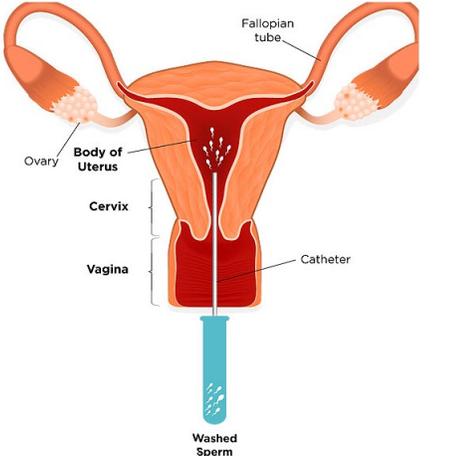
WHAT IS THE PURPOSE OF THE STUDY?

The FIIX Study is looking for couples with unexplained infertility who have been accepted for publicly funded fertility treatment.

In New Zealand, around 30% of infertile couples have unexplained infertility. Currently the funding system requires these couples to have 5 years of infertility before becoming eligible for publicly funded fertility treatment.

We want to compare four cycles of IUI with one cycle of IVF in these couples. We suspect that IUI will have the same number of live births as IVF. By doing this research we hope to provide more opportunities for couples with unexplained infertility to become pregnant.

There are two main fertility procedures available through public funding in New Zealand.

In Vitro Fertilisation (IVF)	Intrauterine Insemination (IUI)
 <p>1) Egg production stimulated by hormone therapy</p> <p>2) Egg retrieved from ovary</p> <p>3) Sperm retrieved</p> <p>4) Egg and sperm combined</p> <p>5) Transferred into the uterus</p> <p><small>Image courtesy of www.redrockfertility.com/what-is-ivf/</small></p>	 <p>Fallopian tube</p> <p>Ovary</p> <p>Body of Uterus</p> <p>Cervix</p> <p>Vagina</p> <p>Catheter</p> <p>Washed Sperm</p>
<p>IVF - an egg is collected from a woman and fertilised with sperm in a laboratory. It then develops before being replaced inside the uterus 3-6 days later.</p>	<p>IUI - sperm is placed directly into the uterus to assist fertilisation of the egg. It is done after oral medication has been given to allow the production and release of 1 to 2 eggs.</p>

STUDY PROCEDURES

Couples who meet the criteria for public funding and agree to take part in The FIIX Study will be randomly allocated to either an IVF or IUI treatment group. As a participant of this study, you will not be able to choose your treatment group. A computer will randomly allocate you to a group. You will be told which group you have been assigned to after you have signed the study consent form.

If you are in the IVF group you will receive your first IVF cycle within three months of enrolment. This will count as your first publicly funded treatment. Your second cycle (if needed) will follow six months after the first cycle starts.

If you are allocated to the IUI group you will receive up to four IUI treatments over six months. If required, you will then receive up to two publicly funded cycles of IVF. Our aim is for all treatment to be finished within 18 months.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Both IUI and IVF procedures will be explained to you in detail at your clinic. You will be asked to provide your consent to carry out the procedure. This will be collected as per normal clinic policy.

If you are assigned to IUI then this involves keeping track of your natural menstrual cycle and taking medication, usually clomiphene, that helps to grow follicles. Follicles are little cysts on your ovaries that contain eggs. You will take the medication for five days, from day 2 to day 6 of your cycle. Blood tests will then be required to check your hormone levels and you will usually have an ultrasound scan of your ovaries and uterus.

If a safe number of follicles develop (usually 3 or less) then you will proceed to the next stage. This involves a small tube with prepared sperm being passed through your cervix and directly into your uterus.

You will receive up to four cycles of this treatment as part of this study. We anticipate that you would complete all four IUI cycles within 6 months.

If you are assigned to the IVF group you will need to have your ovaries stimulated to produce multiple follicles. This is done by giving you injections of different medicines. Once we know you have enough follicles (usually 5-10) we will collect the eggs. Egg collection is a small surgical procedure performed under light sedation. A long thin needle is passed through the top of your vagina and the eggs are collected under ultrasound guidance.

All suitable eggs are then placed in a laboratory dish with sperm and allowed to fertilise. All eggs that are fertilised are checked daily to see if they develop. A single fertilised egg is then placed into the uterus, usually 3 to 6 days after egg collection. A medication is then given as a vaginal pessary to support a potential pregnancy. Any suitable remaining fertilised eggs are frozen. If the initial replacement is unsuccessful then the remaining ones will be thawed, one at a time, and transferred into your uterus until all have been used. We anticipate that all transfers will be completed within 6 months.

If your first cycle of treatment is unsuccessful then you will enter the next stage of the trial. For women in the IVF group, this is a further IVF cycle. For women in the IUI group, this is up to two IVF cycles.

WHAT ARE THE BENEFITS OF THE STUDY?

- You may begin treatment earlier - couples with unexplained infertility currently wait up to 14 months before their treatment commences, this time may be reduced if you participate.
- For those assigned to the IUI group, if pregnancy is achieved then you avoid the more invasive IVF procedure.

WHAT ARE THE RISKS OF THE TREATMENTS?

A disadvantage of the study is that you do not get to choose which treatment you get, although all couples will get up to two cycles of IVF if required. If you want to choose which treatment you have then we suggest that you do NOT participate. If you are randomised to IVF, then your second cycle must be IVF and not IUI in order to continue in the study group.

The usual risks and disadvantages of IUI and IVF apply and these will be further explained to you at time of treatment by your clinician. Please see the summarised table below.

IUI - risks	IVF - risks
Medication allergy	Medication allergy
Infection	Pelvic infection after egg collection
Vaginal spotting	Vaginal or internal bleeding
Pain during catheter insertion	Pain during and after egg collection
Fainting during catheter insertion	Fainting during and after egg collection
Ovarian hyperstimulation syndrome (rare)	Ovarian hyperstimulation syndrome (more common than with IUI)
Multiple pregnancy (twins)	Multiple pregnancy (twins)
Ectopic pregnancy	Ectopic pregnancy
	Injury to internal organs during egg collection
	Respiratory depression (difficulty breathing) during egg collection
	Ovarian torsion (twisting of your ovaries)

WHO PAYS FOR THE STUDY?

Couples who agree to participate in The FIIX Study will not incur any costs. Their treatment will be publicly funded.

WHAT ARE MY RIGHTS?

Participation in The FIIX Study is completely voluntary. You are free to decline to participate or withdraw from the study at any time. You do not need to provide a reason if you withdraw. If you choose not to participate, or you withdraw from the study, this will not affect the care you receive from your fertility clinic.

As a participant in The FIIX Study you have the right to access all information collected about you for the purposes of the study. This information will be stored in a secure electronic system which can only be accessed by investigators and staff at participating clinics.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Any information collected about you for The FIIX Study will be stored electronically for 10 years and then destroyed. Only investigators will be able to access this information. It will be in a format that has no personal identifiers. Published results will be anonymised and readers will not know you took part. When you consent to participate you will be asked if you would like to receive the results of the study sent to you by email.

If you enter the study and decide you no longer wish to continue then you will be able to exit the study. Any future treatment you seek will not be negatively affected. If you have not completed all your treatment when you withdraw, you will be placed on your clinic's current waiting list and your remaining treatment will be completed according to this list.

We encourage participants to think carefully before agreeing to enter the study.

WHAT IF SOMETHING GOES WRONG?

We do not anticipate that participation in this research will increase your risk of injury. If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

WHO DO I CONTACT FOR FURTHER INFORMATION OR IF I HAVE CONCERNS?

Melissa Vercoe Trial coordinator Phone: 09 923 1281 Email: TheFIIXstudy@auckland.ac.nz
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If you want to talk to someone who isn't involved in the study, you can contact an independent health and disability advocate on: Phone: 0800 555 050 Fax: 0800 2 SUPPORT (0800 2787 7678) Email: advocacy@hdc.org.nz	If you require Maori cultural support, you can talk to your whanau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora (Maori Health Team) on: Phone: 09 486 8324 ext 2324	You can also contact the health and disability ethics committee (HDEC) that approved this study on: Phone: 0800 4 ETHICS (0800 438 4427) Email: hdecs@moh.govt.nz
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