

CONSENT FORM

PARENTERAL INDUCTION OF OVULATION (PIO)/ SUPEROVULATION AND INTRAUTERINE INSEMINATION (IUI)/ TIMED INTERCOURSE

ACCOUNT NO.
NRIC NO.
NAME
ADDRESS
SEX/BIRTH DATE/RACE
DATE AND TIME OF ADMISSION

What is parenteral induction of ovulation (PIO)/superovulation and intrauterine insemination (IUI)/timed intercourse?

PIO/superovulation is a procedure where hormone injections are given to stimulate one to three follicles in the ovaries until they are of an adequate size. Sperm/donated sperm is then placed inside the woman's uterus via intra-uterine insemination (IUI) or intercourse will be timed with the aim of achieving pregnancy.

Why do I need PIO/superovulation and IUI/timed intercourse?

PIO/superovulation and IUI/timed intercourse is also used as fertility treatment for any of the following conditions/reasons:

1. Mild reduction in sperm
2. Sexual dysfunction where there is difficulty with penetration
3. When the spouse is away and hence intercourse is not possible
4. When there is failure of oral fertility medication to induce ovulation
5. Infertility of unknown cause
6. You or your spouse has subfertility
7. Other indications deemed medically suitable by your doctor

The sperm to be inseminated may come from your husband or from a donor if you have opted for one.

The probability of conception with IUI is about 10 – 15%.

What does it involve?

Prior to initiating IUI treatment, you and your husband or the donor of the sperm will have to undergo blood tests and screening for infectious diseases. In addition, you will have to have:

- Assessment of patency of the fallopian tube and assessment of cavity of the womb. This could be performed via ultrasound, X-ray, or surgery. IUI/timed intercourse is not suitable for women in whom both fallopian tubes are blocked.
- Blood tests and ultrasound to assess your ovarian reserve to help gauge how well you will respond to the hormonal medication.

Hormone injections (and sometimes other medications) are administered to stimulate the ovaries in order to produce 1-3 follicles, thereby, increasing the chance of achieving pregnancy. A transvaginal ultrasound scan is used to monitor the growth of the follicles. A follicle is a fluid-filled structure in the ovary that contains a developing egg. The hormone, Human Chorionic Gonadotropin (hCG), is administered to stimulate the release of eggs from the follicles when the follicles are of sufficient size to synchronise the IUI/timed intercourse. This process may take 2 to 3 weeks. Afterwards, IUI or intercourse will be timed accordingly.

If you are proceeding with timed intercourse, you should have sexual intercourse the day after the hCG injection.

If you are proceeding with IUI, your husband must deliver his semen sample to the Hospital (the SingHealth institution where the Procedure is performed). The semen sample will be processed by the laboratory in order to separate the semen from the seminal fluid and select active motile sperm. A speculum is used to visualise the neck of the uterus and a catheter is then used to inject the processed sperm directly into the uterus. The IUI procedure takes 5-10 minutes and involves minimal discomfort. You may be given a course of antibiotics if you are at risk of infection.

IUI is scheduled only on working days. The development of the egg is not predictable and hence if the procedure cannot be performed during working days, you will be guided for timed intercourse.

What precautions must I take for the procedure?

Please inform your doctor if you have any medical illnesses. Before the procedure, please inform your doctor if any of the following are applicable:

1. You have a history of allergy or reaction to any medications or drugs.
2. You have a history of bleeding or clotting disorders.

Please check and confirm whether **all** medications, including supplements you are taking for other ailments are suitable to be taken in early pregnancy.

What are the risks and complications of the procedure?

The IUI / timed intercourse may need to be abandoned due to the following reasons:

1) **Too many follicles developing**

The aim of the procedure is to stimulate 1 – 3 follicles. However, there is an approximate 2.6 – 6.6% chance that too many follicles may develop. Under these circumstances, there is 3.4 –10% risk of high order multiple gestations (pregnancy with triplets or more). The option will be to abandon the procedure or convert this into an in-vitro fertilisation (IVF) cycle. In an IVF cycle, the oocytes (egg cell) will be retrieved and fertilized in the laboratory. The fertilized egg will then be transferred back into the womb. You will need to sign a separate consent form to proceed with IVF.

2) **Insufficient follicular development**

Follicular development can be unpredictable. The risk of none or insufficient follicular development is less than 1%. In such an event, the treatment cycle may have to be prolonged and, in some cases, abandoned.

3) **Inability to perform intrauterine insemination**

This occurs rarely and could be due to technical difficulty or anatomical distortion. The semen will be injected into the cervix or vagina instead.

4) **IUI day coincides with non-working days**

IUI is scheduled only on working days. The development of the egg is not predictable and hence if the procedure cannot be performed during working days, you will be guided to attempt conception naturally without the IUI.

5) **Uterus lining not developed**

If your uterus lining is not appropriately developed, it will be difficult to conceive even after IUI. Hence, the procedure may need to be abandoned.

6) Missed ovulation

When the timing of the ovulation (the time when your egg is released) is missed despite monitoring of the cycle, the procedure may need to be abandoned.

A. Risks and complications associated with PIO

1) Multiple Pregnancies

Multiple pregnancies (pregnancies with twins or more) may occur 5 – 10% of the time.

This may pose certain risks to the foetus(es) and mother, such as the following:

- Risks to the foetus(es) include increased risk of miscarriage, preterm labour, and prematurity as well as attendant complications, which require care in the intensive care unit (ICU) such as respiratory distress, brain damage, including loss of life.
- Risks to the mother include higher risks of morning sickness (nausea and vomiting), miscarriage, caesarean section, preterm delivery, hypertension, anaemia, and diabetes. The mother will also be at greater risk of social, psychological, and financial stress during and after delivery. You are advised to see the Medical Social Worker and/or Psychiatrist if necessary.

2) Ovarian Hyperstimulation Syndrome (OHSS)

If you are a high responder to the medication, you might experience diarrhoea, abdominal pain, abdominal bloating, nausea, vomiting, or increased waist size. This is very rare with oral fertility medications.

3) Adverse drug reaction

Some patients may experience unwanted, uncomfortable, and sometimes dangerous effects of a drug (adverse drug reaction). Although uncommon, this may necessitate admission to the hospital for further observation or treatment.

B. Risks and complications associated with IUI

1) Bleeding

Some bleeding and discomfort are expected and should resolve over time.

2) Infection

This is a rare occurrence. If you are at risk of infection, a preventive course of antibiotic will be administered to you. If you still develop infection after the procedure, further antibiotic treatment and hospitalisation will be needed.

3) Uterine perforation

Where there is difficulty finding the path into the womb, the catheter may pierce the uterus. This complication rarely occurs. When it does occur, further hospitalisation, antibiotic course or surgery may be needed.

C. Risks and complications inherent in any pregnancy

1) Risks associated with older patients

For women above 35 years old at the estimated date of delivery, there is also an increased risk of genetic anomalies in the foetus, e.g., having a baby with Down's Syndrome.

Pregnancy rate is lower for women above 40 years old and there is a higher risk of developing complications, such as hypertension, diabetes, or delivery requiring caesarean section.

Also, there may be impact on the welfare of the child due to parenthood at an older age, such as:

1. Social acceptance of the child having older parents, including the large age gap between the parents and the child; and
 2. The possibility of the child having to care for aged / ill parents or having to face the loss of one / both parent(s) during their schooling years or early in their careers
- 2) Risks of ectopic pregnancy, miscarriage, and fetal abnormality
The risks of ectopic pregnancy (pregnancy occurring outside the normal cavity of the uterus), miscarriage and fetal abnormality are similar to that of a spontaneous conception.

What can I expect after the procedure?

You may request for medical leave for the day of IUI. Unless advised not to do so, you may have sexual intercourse the same day and the next to increase your chance of pregnancy. You may continue with your usual daily activities. Hormonal medication will be prescribed to support the pregnancy. You may be required to do a pregnancy test at the hospital.

Psychosocial Support

Fertility treatment may have an impact on your emotional and mental well-being. During treatment, you may experience a range of emotions and may find difficulty managing them.

Do inform your healthcare professional if you would like to speak to a counsellor at any time before or during the treatment process.

Reporting Outcomes

The Hospital is required to collect and report to MOH cycle-specific data, pregnancy and live-birth details of all AR cycles performed at the Hospital for the purpose of statistical reporting and research.

All information received, which is subject to medical confidentiality, shall be treated as confidential.

To ensure accurate and timely reporting of data to MOH, the Hospital may contact you for additional follow-up.

What are my options?

1. The option of no treatment.
2. If you have endometriosis, surgery can be performed to remove cysts in the ovaries or affected tissue. However, endometriosis can recur, and repeated removal of cysts may reduce remaining ovarian tissue and ovarian reserve.
3. Laparoscopic ovarian drilling, injection to stimulate ovulation or lifestyle changes to achieve weight loss in some cases of Polycystic Ovarian disease. Polycystic Ovarian disease is a common cause of anovulation (i.e., difficulty with egg release) and usually fertility drugs would have been used as the first line of treatment.
4. In-vitro fertilization (IVF), a process by which egg cells are fertilised by sperm outside of the womb (in-vitro). The embryo (fertilised egg) is then transferred into the womb to achieve pregnancy or cryopreserved (frozen) for future use.
5. Child adoption.
6. You can discuss these options in more details with your doctor.

Others (to be filled by Healthcare Professional) [if applicable]

Part I – Patient’s and Husband’s Declaration

1. I, _____ (NRIC/Passport No. _____)
(hereinafter referred to as “Patient”), and

I, _____ (NRIC/Passport No. _____)
(hereinafter referred to as “Husband”)

have read this information sheet and confirm that we understand the nature, purpose, risks, complications, and alternatives with regard to the following “Procedure”:

Parenteral induction of ovulation (PIO)/Superovulation with intrauterine insemination (IUI)

Parenteral induction of ovulation (PIO)/Superovulation with timed intercourse

2. We declare that we are still legally married up to the point of insemination and if there is any change in status, we will update the Hospital (the SingHealth institution where the Procedure is performed).
3. We acknowledge that the risks and complication(s) listed are not intended to be exhaustive. We have had an opportunity to ask for more information about (i) the above-mentioned risks and complications; (ii) the risks and complications in general; and (iii) specific concern(s) of relevance to us.
4. We have also decided that, in the event of overstimulation, we will:
 - Abandon the Procedure**
 - Convert the Procedure into In-Vitro Fertilisation (separate consent form to be signed)**
 - Undecided, to be decided later**
5. We consent to any other treatment and monitoring procedures deemed necessary; and further or alternative procedural measures as may be found to be necessary during the course of the Procedure.
6. We consent to the use of drugs and medicines as may be deemed advisable or necessary for this Procedure.
7. We acknowledge that no representation has been made to us that the Procedure will be performed by any particular healthcare professional.
8. We hereby consent to undergo the Procedure.
9. We understand that this consent form is valid for 3 months from the date of consent.
10. We understand that all treatment details and outcome resulting from this Procedure will be notified to the Ministry of Health, Singapore, for the purpose of statistical reporting and research. We consent to the release of such information to the Ministry of Health.
11. We undertake to notify the Hospital of any birth(s) resulting from this Procedure within 28 days of delivery.
12. We understand and agree that the Procedure will be performed by the appropriate SingHealth institution and the Patient will be admitted and/or registered as a patient of that SingHealth institution.