Shanghai JiAi Genetics & IVF Institute

Study: A randomized trial comparing the effect of immediate versus delayed frozen-thawed embryo transfer following a stimulated IVF cycle

PATIENT INFORMATION AND CONSENT

STUDY TITLE: A randomized trial comparing the effect of immediate versus delayed frozen-thawed embryo transfer following a stimulated IVF cycle

You are being invited to participate in the above named research study. Before you decide 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. 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.

What is the purpose of the study?

Information regarding the optimal timing for frozen-thawed embryo transfer (FET) following a stimulated in vitro fertilization (IVF) is lacking. One option is to perform FET in the first cycle following the stimulated IVF cycle, i.e. immediate transfer. Another option is to postpone FET for at least one menstrual cycle, i.e. delayed transfer.

Several retrospective studies showed similar success for these two options. Another retrospective analysis showed higher clinical pregnancy and live birth rates in the delayed group. Since these studies are all retrospective and the findings are contradictory, a randomized study is needed to provide good evidence to guide the clinical practice.

This randomized study aims to compare the ongoing pregnancy rate of immediate versus delayed FET following a stimulated IVF cycle.

Why have I been chosen?

You are chosen because

- You are <=43 years of age at the time of IVF treatment.
- You underwent IVF with a standard stimulation.
- You have at least one frozen embryo or blastocyst.
- You are undergoing the first FET following ovarian stimulation in IVF.

You will not be included in this study if

- You are using mild stimulation or natural cycle in the IVF treatment.
- You had severe ovarian hyperstimulation syndrome during IVF treatment.
- You had pre-implantation genetic diagnosis treatment.
- You are using donor oocytes.

- Presence of hydrosalpinx which is not surgically treated or endometrial polyp on scanning during ovarian stimulation.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you do not join or if you quit the study, you will still receive the standard treatment as other patients in our Department.

What will happen to me if I take part?

If you agree to participate in the study, you will be randomized by a computer-generated list into one of the two groups:

(1) ***Immediate group***: Your thawed embryos will be transferred into your womb in the first cycle following the stimulated IVF cycle.

(2) ***Delayed group*****:** Your thawed embryos will be transferred into your womb at least in the second cycle following the stimulated IVF cycle.

The groups are selected by a computer that has no information about the individual, i.e. by chance. We will compare the outcomes between the two groups at the end of the study.

How many other people will be participating in the study?

We plan to recruit 724 women in this study.

What are the disadvantages and risks of taking part?

There should be no safety concern. No specific risk is expected. No extra charge or visit is required for participating in the study.

What are the benefits of taking part?

No payment will be made to you for this study.

What will happen to the results of the research?

The results of the study will be presented in international meetings and published in a medical journal. You will not be identified in any report or publication.

Confidentiality and privacy

The investigators have always maintained a strict privacy policy. We never sell, trade or otherwise share your details with any sources. All correspondence to the department is held confidentially; furthermore, at no time will your personal and/or identifying information be shared outside of our organization, for any reason.

You have the rights of access to personal data and publicly available study results, if and when needed. Under the laws of China, you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of China, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study.

By consenting to participate in this study, you expressly authorize:

- the principal investigator, the research team and the Institutional Review Board responsible for overseeing this study to get access to, to use, and to retain your personal data for the purposes and in the manner described in this informed consent process; and
- the relevant government agencies (e.g. the Shanghai Municipal Commission of Health and Family Planning) to get access to your personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

Contact for further information

For questions about the study or reporting of adverse events, you may contact the Principal Investigator, Dr Li He at telephone no.13817223099. The phone number of Shanghai JIAI Genetics & IVF is 021-63459977.

Thank you for your time to read this information sheet and for taking part in the study.

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PATIENT CONSENT FORM

Patient Identification Number for this trial: _____

Title of Project: A randomized trial comparing the effect of immediate versus delayed frozen-thawed embryo transfer following a stimulated IVF cycle

1. We confirm that we have read and understood the information sheet for the above study and have had the opportunity to ask questions.
2. We understand that our participation is voluntary and that we are free to withdraw at any time, without giving any reason, without our medical care or legal rights being affected.
3. We understand that sections of any of our medical notes may be looked at by responsible individuals from regulatory authorities where it is relevant to our taking part in research. We give permission for these individuals to have access to our records.
4. We agree to take part in the above study.
5. We give permission to the investigators to retrieve pregnancy and delivery data.

Patient's signature	Patient's name	Date
Patient's husband signature	Patient's husband name	Date
Investigator's signature	Investigator's name	Date
Witness's signature	Witness's name	Date