

# Study on the prediction of embryo implantation success with the method of pinopodes detection in IVF-ET treatment

<b>Submission date</b> 20/09/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/11/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/07/2018	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In order for a woman to become pregnant, the fertilised egg must attach (implant) itself to the lining of the womb (endometrium). In order for this to be successful, the implantation must happen within a small window of opportunity, known as the “implantation window”. It is only within the implantation window that the endometrium is receptive, and the fertilised egg (embryo) can attach to it. In vitro fertilisation (IVF) is a technique used to help people with fertility problems to have a baby. During IVF, the egg is fertilised by the sperm outside of the body to create an embryo and then returned to the woman’s uterus to develop. Although IVF has become more and more successful in recent years, there is still a relatively high failure rate. In many cases, some of the embryos are frozen so that they can be used in the next cycle of IVF (frozen embryo transfer). A possible reason for this is that the implantation window is being missed, and so the embryos are not able to attach. Pinopodes, are large rounded nodules found on the endometrium. It is thought that pinopode production is related to the hormone progesterone. Studies have shown that the presence of lots of pinopodes is linked to successful implantation. The aim of this study is to find out the whether detecting pinopodes can help to predict the window of implantation of endometrium, increasing the number of implantations.

### Who can participate?

Women aged below 35 years, in their first round of IVF treatment.

### What does the study involve?

All participants receive hormone replacement therapy (injection of natural female hormones) from day 3 of their menstrual cycle. They receive injections of 3mg Oestradiol valerate (a female oestrogen hormone) for 7 days, increasing to 4mg twice a day for the next 6 days. The endometrium (lining of the womb) is now a 8mm in thickness, and a sample is taken so that it can be looked at under a microscope to look for pinopodes. The amount of pinopodes found are then used to predict the likelihood of the woman becoming pregnant in her next cycle, when she undergoes IVF. In the next cycle, the woman receives the same hormone replacement therapy as

well as having a thawed embryo (frozen from a previous cycle) transferred into her womb. The amount of women who successfully become pregnant is then recorded and compared to the predictions from the pinopode detection.

What are the possible benefits and risks of participating?

Participants may benefit from a better chance of pregnancy, if the detection of pinopodes is accurate. There are no significant risks of participating, however participants may experience vaginal bleeding for infection after biopsy.

Where is the study run from?

Sir Run Run Shaw Hospital (China)

When is the study starting and how long is it expected to run for?

October 2015 to May 2016

Who is funding the study?

Health and Family Planning Commission of ZheJiang Province (China)

Who is the main contact?

Ms Lijuan Zhao

## Contact information

### Type(s)

Scientific

### Contact name

Ms Lijuan Zhao

### ORCID ID

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## Additional identifiers

## Study information

### Scientific Title

The pinopodes detection could predict the endometrial receptivity in infertile women

### Study objectives

Pinopodes could be considered as a potential biological marker of endometrial receptivity. Detecting the pinopodes may have great clinical value in predicting the window of implantation of endometrium.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethic committee Sir Run Run Shaw Hospital, 30/10/2015, ref: 20151105-9

## **Study design**

Prospective cohort study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic

## **Health condition(s) or problem(s) studied**

Infertility

## **Interventions**

Frozen-thawed embryo transfer (FET) is a safe and cost-effective adjunct to In Vitro Fertilization (IVF) treatment. Endometrial preparation protocols for FET commonly include natural and hormone replacement treatment (HRT). In the study, all patients undergo a modeling HRT cycle. That is, from day 3 of the menstrual cycle with Oestradiol valerate (Progynova; Schering AG, Berlin, Germany) 3 mg two times a day for 7 days, increasing to 4 mg two times a day for the next 6 days. When the endometrium reached a thickness of 8mm, then progesterone were consecutively injected IM 80mg for 6 days in all patients. Endometrial biopsies are taken on the day after the last progesterone injection, for pinopode detection by Scanning Electron Microscopy (SEM). The results from the pinopode detection will be used to predict the outcome of the next HRT-FET cycle the patients undergo. In the next cycle, all patients will undergo conventional HRT-FET regimes. All subjects were followed up whether clinical pregnancy in 5 weeks -7 weeks after FET operation.

## **Intervention Type**

Other

## **Primary outcome(s)**

Embryo implantation rate is determined by measuring the number of gestational sacs present on ultrasound divided by the number of embryos transferred 5-7 weeks after embryo transfer.

## **Key secondary outcome(s)**

Clinical pregnancy rate is determined by testing serum hCG levels and transvaginal ultrasound scanning 5-7 weeks after embryo transfer.

## **Completion date**

30/06/2017

## **Eligibility**

### **Key inclusion criteria**

1. Female participants only
2. Aged below 35 years
3. Tube factors or male factor infertility
4. First IVF treatment

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

1. Uterine organic diseases such as uterine fibroids or denomyosis
2. Internal and external genital malformation and hydrosalpinx

**Date of first enrolment**

30/10/2015

**Date of final enrolment**

01/05/2016

**Locations****Countries of recruitment**

China

**Study participating centre****Sir Run Run Shaw Hospital**

Assisted Reproduction center  
Department of Obstetrics and Gynecology  
Zhejiang University School of Medicine  
3 Qingchun E Rd  
Hangzhou  
China  
310016

**Sponsor information****Organisation**

Health and Family Planning Commission of ZheJiang Province

ROR

<https://ror.org/010qdt721>

## Funder(s)

**Funder type**

Government

**Funder Name**

Health and Family Planning Commission of ZheJiang Province

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2017		Yes	No