ISRCTN26300668 https://doi.org/10.1186/ISRCTN26300668

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

Submission date
20/09/2015

Recruitment status
No longer recruiting

Registration date
26/11/2015

Overall study status
Completed

Last Edited
10/07/2018

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 toe 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?
Heath and Family Planning Commission of ZheJiang Province (China)

Who is the main contact?
Ms Lijuan Zhao

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

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
Heath and Family Planning Commission of ZheJiang Province

ROR
https://ror.org/010qdt721

Funder(s)

Funder type
Government

Funder Name
Heath 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?
Results article	results	01/12/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes