

# The comparison of pregnancy outcomes in hydrosalpinx patients treated with salpingectomy and proximal tubal occlusion prior to in vitro fertilization embryo transfer

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<b>Registration date</b> 10/12/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/12/2016	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Women with a blocked, fluid-filled Fallopian tube (hydrosalpinx) have lower pregnancy rates (tubal infertility) and increased miscarriage rates after in vitro fertilization (IVF) treatment. Laparoscopic salpingectomy (surgical removal of the fluid-filled tube) is the current standard treatment. Laparoscopic proximal tubal occlusion (surgery to block off the fluid-filled tube) is an alternative treatment to laparoscopic salpingectomy. The aim of this study is to compare pregnancy outcomes after the two treatments.

### Who can participate?

Women aged 18-41 with tubal infertility planning to undergo IVF

### What does the study involve?

Participants are randomly allocated to undergo either laparoscopic salpingectomy or laparoscopic proximal tubal occlusion before undergoing IVF. Embryo transfers are performed two months after surgery. Participants are routinely called for a blood sample 14 days after the hCG trigger (to trigger the ovaries to release eggs) to measure human chorionic gonadotropin (hCG) hormone levels, and to confirm whether pregnancy has occurred. An ultrasound examination is arranged 5 weeks after embryo transfer for participants with a positive hCG test to confirm the pregnancy. Patients are followed up until pregnancy is completed.

### What are the possible benefits and risks of participating?

The treatments may improve pregnancy rate and reduce the ectopic pregnancy and miscarriage rate. However, the treatments are invasive and involve risks related to anaesthesia and surgery.

### 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?

January 2016 to December 2019

Who is funding the study?

Zhejiang Province Health High-Level Innovative Talents Training (China)

Who is the main contact?

Mrs Songying Zhang

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Songying Zhang

### Contact details

3# Qing Chun East Road

Hangzhou

China

310016

## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

The comparison of pregnancy outcomes in hydrosalpinx patients treated with salpingectomy and proximal tubal occlusion prior to in vitro fertilization embryo transfer: a randomized controlled study

### Study objectives

Many retrospective studies reported significantly lower implantation and pregnancy rates in patients with hydrosalpinges when compared with other types of tubal disease, as well as increasing rates of spontaneous abortions and ectopic pregnancies. The hypothesis is that the pregnancy outcomes of hydrosalpinx patient prior to in vitro fertilization embryo transfer will be better in the salpingectomy group than the proximal tubal occlusion group.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Medical ethics committee, Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University, 16/03/2015

### Study design

Single-centre prospective randomized controlled study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Hydrosalpinx

## **Interventions**

Participants are randomised to undergo either modified laparoscopic salpingectomy or modified proximal tubal occlusion prior to in vitro fertilization embryo transfer. Prophylactic antibiotics are transfused to all patients.

Group 1: Undergo the modified laparoscopic “core-pulling” salpingectomy. All salpingectomies are performed laparoscopically.

Group 2: Undergo the modified laparoscopic proximal tubal occlusion. Proximal tubal occlusion is also performed laparoscopically.

Embryo transfers are performed two months after surgery. Patients are routinely called for a blood sample 14 days after hCG trigger to measure human chorionic gonadotropin (hCG), and to confirm whether pregnancy has occurred. An ultrasound examination is arranged 5 weeks after ET for subjects with a positive hCG test to verify the exact location and viability of the pregnancy. Patients are followed up until pregnancy is completed.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

1. Clinical pregnancy, defined as gestation sac and/or fetal pole measured using ultrasound scan at 22 days after embryo transfer
2. Ongoing pregnancy, defined as a fetal heartbeat measured on ultrasound beyond 10-weeks gestation

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

1. Implantation rate, defined as the number of gestational sacs on ultrasound divided by the number of embryos transferred, measured using ultrasound scan at 22 days after embryo transfer
2. Ectopic pregnancy at any extrauterine site (considered as an implanted embryo), measured using ultrasound scan at 22 days and 35 days after embryo transfer
3. Miscarriage, measured during the first trimester
4. Live birth rate, measured at birth
5. Ovarian reserve, measured using FSH levels on cycle day 2-3 before and 3 months after the laparoscopic surgery

## **Completion date**

31/12/2019

# Eligibility

## Key inclusion criteria

1. Women with tubal infertility planning to undergo IVF
2. 18-41 years old

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Upper age limit

41 years

## Sex

Female

## Key exclusion criteria

1. Endometriosis
2. Prior ovarian surgery
3. Diminished ovarian reserves
4. Polycystic ovarian syndrome (PCOS)

## Date of first enrolment

01/01/2017

## Date of final enrolment

31/12/2018

# Locations

## Countries of recruitment

China

## Study participating centre

Sir Run Run Shaw Hospital

3# Qing Chun East Road

Hangzhou

China

310016

# Sponsor information

## Organisation

Health Bureau of Zhejiang Province

## Funder(s)

### Funder type

Government

### Funder Name

Zhejiang Province Health High-Level Innovative Talents Training (China)

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Mrs Songying Zhang

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes