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

Submission date
25/11/2016

Recruitment status
No longer recruiting

Registration date
10/12/2016

Overall study status
Completed

Last Edited
07/12/2016

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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310016

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
12/01/2016

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
41 Years

Sex
Female

Target number of participants
100

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
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310016

Sponsor information

Organisation
Health Bureau of Zhejiang Province

Sponsor details
216# Qingchun Road
Hangzhou
China
310006

Sponsor type
Government

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date
31/12/2020

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