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A comparison of Cook balloon and coil in the prevention of adhesion reformation following hysteroscopic surgery for Asherman syndrome

Submission date
28/01/2013

Recruitment status
No longer recruiting

Registration date
15/02/2013

Overall study status
Completed

Last Edited
06/05/2015

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
Asherman syndrome is a condition of uterine distortion resulting in amenorrhoea or hypomenorrhoea, infertility and recurrent pregnancy loss. The re-adhesion rate is high after surgical intervention. In our previous study, we compared the use of three different approaches to preventing recurrence of intrauterine adhesions following treatment of Asherman syndrome, namely, an intrauterine contraceptive device(IUD), a specially designed intrauterine balloon and hyaluronic acid gel, in addition to a control group. Both intrauterine balloon group and IUD group achieved significantly greater amount of reduction in the adhesion score than that of the hyaluronic acid gel group and control group. There was no significant difference in results between the balloon and IUD groups. The aim of this study is to compare the adhesion reformation prevention efficacy between balloon and IUD.

Who can participate?
Woman with confirmed uterine adhesion with moderate or severe degree by hysteroscopic examination and history review for the first time in Sir Run Run Shaw hospital is to be recruited. All the participants should be younger than 40 years old, having potential conceiving requirement.

What does the study involve?
The same hysteroscopic adhesion resection will be performed on all patients, and then they will be randomly allocated to two groups.
Group 1: fitting of an IUD (copper coil, Shandong contraceptive instrument company, China)
Group 2: fitting of a specially designed intrauterine balloon (Cook Company, UK)
Both devices will be removed in 1 week. In all cases hormone therapy is commenced from the day of operation, consisting of oestradiol valerate at a dose of 6 mg per day for 21 days with the addition of medroxyprogesterone acetate at a dose of 6 mg per day for the last 7 days of the oestrogen therapy. Following the withdrawal bleed, the hormone therapy was repeated for another cycle. A second look hysteroscopy was carried out in the early proliferative phase, 1-2 months after the initial operation.

What are the possible benefits and risks of participating?
The participants will receive comprehensive treatment for Asherman syndrome. For the intrauterine balloon is licensed for use for 24 hours, fitting in the uterine cavity for 7 days may increase the infectious risk. Other side effects are the complications related to the surgery.

Where is the study run from?
Reproductive medical center of Sir Run Run Shaw hospital, medical school, Zhejiang University, China

When is the study starting and how long is it expected to run for?
The study was started in April 2012 and will run 2 years or until 100 cases are recruited.

Who is funding the study?
Zhejiang Provincial Bureau of Health, China

Who is the main contact?
Dr Xiaona Lin
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A comparison of intrauterine balloon stent and intrauterine contraceptive device in the prevention of adhesion reformation following hysteroscopic surgery for Asherman syndrome: a randomized case-control study

Study objectives
Asherman syndrome is a condition of uterine distortion resulting in amenorrhoea or hypomenorrhoea, infertility and recurrent pregnancy loss. The re-adhesion rate is high after surgical intervention. The aim of this study is to compare the adhesion reformation prevention efficacy between balloon and IUD.

The principal questions of the research are the uterine adhesion reformation rate and following pregnancy rate after surgical resection of adhesion. We hypothesise the adhesion reformation rate is lower when the Cook balloon is inserted comparing to IUD, whereas the pregnancy rates are similar in two groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board of the Sir Run Run Shaw Hospital, Hangzhou, China, January 2013

Study design
Single center randomized case-control study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Asherman syndrome

Interventions
In all cases hysteroscopy is carried out under general anaesthesia which confirmed the presence of intrauterine adhesions. Hysteroscopy examination is carried out by two reproductive surgeons and the case is recruited if the AFS score is equal or more than 5. A 4.5 mm hysteroscope (Storz, Germany) is used in each case. The adhesions are divided with the use of hysteroscopic scissors. The procedures are carried out under ultrasound or laparoscopic guidance when necessary.

At the end of the procedure the patients were allocated to one of the two groups according to the randomized table:
1. Fitting of an IUD (copper coil, Yandai contraceptive instrument company, China)
2. Fitting of a specially designed intrauterine balloon (Cook medical company, Australia)

In all cases hormone therapy is commenced shortly after the operation, consisting of oestradiol valerate at a dose of 6 mg per day for 21-28 days with the addition of medroxyprogesterone acetate at a dose of 6 mg (check dose) per day for the last 7-10 days of the oestrogen therapy. All of the devices inserted will be removed in 7 days. Following the withdrawal bleed, the hormone therapy is repeated for another cycle.

A second look hysteroscopy is carried out in the early proliferative phase, 1-2 months after the initial operation, assessing the adhesion score by AFS criteria. Should recurrence of intra-uterine adhesions be confirmed during the second look hysteroscopy, a repeat adhesiolysis procedure would be performed.

Intervention Type
Device

Primary outcome measure
The severity and extent of intrauterine adhesions were scored according to a classification system recommended by the American Fertility Society (AFS) (1988 version). A score of 1-4 was considered to represent mild adhesions, a score of 5-8 was considered to represent moderate adhesions and a score of 9-12 as representing severe adhesions.

Secondary outcome measures
Pregnancy rates in both groups after surgery

Overall study start date
01/02/2013

Completion date
30/07/2014

Eligibility

Key inclusion criteria
1. Woman with confirmed uterine adhesion with moderate or severe degree [American Fertility Society (AFS score range 5~12)] by hysteroscopic examination and history review for the first time in Sir Run Run Shaw hospital is to be recruited.
2. All the participants should be >=18 years and younger than 40 years old, having potential conceiving requirement

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Female

Target number of participants
200 cases. The enrollment will be stopped until 200 cases completed or the significant difference appears.

Key exclusion criteria
1. Older than 40 years old
2. The AFS score less than 5
3. Who doesn't want to get pregnant
4. Who has received hysteroscopic adhesive resection before
5. Who can't follow up according to the study protocol

Date of first enrolment
01/02/2013

Date of final enrolment
30/07/2014

Locations

Countries of recruitment
China

Study participating centre
Sir Run Run Shaw Hospital
Hangzhou
China
310016

Sponsor information

Organisation
Health Bureau of Zhejiang Province (China)

Sponsor details
216# CQingchun Road
Hangzhou
China
310002

Sponsor type

Government

Website
http://www.zjwst.gov.cn

Funder(s)

Funder type
Government

Funder Name
Zhejiang Health Science Foundation (China) (2011KYA084)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2015		Yes	No