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Effect of platelet-rich plasma gel on intrauterine adhesions

Submission date
24/06/2020

Recruitment status
No longer recruiting

Registration date
02/07/2020

Overall study status
Completed

Last Edited
02/09/2024

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
Intrauterine adhesions (IUAs) form when scar tissue builds up between the inner walls of the uterus causing the walls to bind together. The incidence rate of IUA is high after multiple artificial abortion and curettage. It severely results in amenorrhea (stopped periods), infertility and recurrent pregnancy loss. Although a surgical procedure called transcervical resection of adhesion (TCRA) can improve the uterine morphology, the postoperative re-adhesion rate reaches 62.5%. Platelet-rich plasma (PRP) contains a large amount of growth factors. Once activated by thrombin and calcium chloride, these growth factors will play roles in promoting tissue growth. Autologous platelet-rich gel (APG) is a gelatinous substance formed by mixing thrombin and calcium with PRP, which is obtained from peripheral venous blood of the patient. The aim of this study is to research the application of APG in preventing recurrence of IUA after TCRA.

Who can participate?
Women between 18 and 40 years old with moderate or severe degree intrauterine adhesion and no previous history of hysteroscopic adhesiolysis (a procedure used to treat adhesions)

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:
APG group: APG is injected into the uterine cavity after TCRA and an intrauterine device (IUD) is fitted
Control group: medical chitosan is injected into the uterine cavity and an IUD is fitted
All the patients undergo TCRA between 3 to 7 days after menstruation. In all cases hormone therapy is started from the day of the operation, consisting of Femoston (estradiol 2 mg /dydrogesterone 10 mg) at a dose of two tablets per day for 28 days. Following the withdrawal bleed, the hormone therapy was repeated for another cycle. A second look hysteroscopy is carried out 2 months after the initial operation, assessing the adhesion score. Both IUDs will be removed at the second look. Should recurrence of intrauterine adhesions be confirmed during the second look hysteroscopy, a repeat adhesiolysis procedure is performed.

What are the possible benefits and risks of participating?
The benefit of participating is to improve the degree of intrauterine adhesions. The risk of participating is the infection risk. Other side effects are the complications related to the surgery.

Where is the study run from?
Shengjing Hospital of China Medical University (China)

When is the study starting and how long is it expected to run for?
January 2019 to May 2021

Who is funding the study?
Shengjing Hospital of China Medical University (China)

Who is the main contact?
Prof. Guangwei Wang
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
A comparison of autologous platelet-rich plasma gel and medical chitosan in the prevention of adhesion after hysteroscopic adhesiolysis

Acronym
PRPIUA

Study objectives
The adhesion recurrence rate is lower when the platelet-rich plasma (PRP) is injected into the uterine cavity after TRCA compared to medical chitosan, whereas the pregnancy rates are similar in two groups. The hypothesis of the study is that women with moderate to severe intrauterine adhesion may benefit from exposure to growth factors known to be present in PRP.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/01/2019, Institutional Review Board of the Shengjing Hospital of China Medical University (No. 36 Sanhao Street, Heping District, Shenyang, China, 110004; +86 (0)24 96615 10027; llwyh@sj-hospital.org), ref: 2019PS014J

Primary study design
Interventional

Study design
Single-center randomized study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Intrauterine adhesion

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 same hysteroscopic adhesion resection will be performed on all patients, and then they will be randomly allocated by computer-generated numbers to two groups. The procedures of TCRA are carried out under ultrasound or laparoscopic guidance when necessary.

APG group: APG 5 ml is injected into the uterine cavity after TRCA and an IUD is fitted
Control group: medical chitosan 5 ml is injected into the uterine cavity and an IUD is fitted

All the patients undergo TRCA between 3 to 7 days after menstruation. In all cases hormone therapy is commenced from the day of operation, consisting of Femoston (estradiol 2 mg /dydrogesterone 10 mg) at a dose of two tablets per day for 28 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, 2 months after the initial operation, assessing the adhesion score by AFS criteria. Both IUDs will be removed at the second look. Should recurrence of intrauterine adhesions be confirmed during the second look hysteroscopy, a repeat adhesiolysis procedure would be performed.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The severity and extent of intrauterine adhesions scored according to a classification system recommended by the American Fertility Society (AFS) (1988 version), measured 2 months after surgery

Key secondary outcome(s)
Pregnancy rates measured using ultrasound after the operation until 1 year after the termination of the clinical trial

Completion date
31/05/2021

Eligibility

Key inclusion criteria
1. Moderate to severe intrauterine adhesion (AFS score ≥5)
2. No previous history of hysteroscopic adhesiolysis
3. Written consent obtained
4. Agreement to have second-look hysteroscopy
5. All the participants should be ≥18 years and younger than 40 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria

1. Pregnancy or breastfeeding women
2. Minimal adhesion(AFS5)
3. Previous history of hysteroscopic adhesiolysis
4. Highly allergic constitution or a history of severe allergic to thrombin
5. Systemic infection or severe local infection
6. Amenorrhea due to ovarian hypofunction or other causes
7. Severe cardiopulmonary disease, liver and kidney dysfunction and other severe underlying disease
8. Poor compliance (cannot finish the trial) or the investigator believes that the patient is not appropriate for treatment

Date of first enrolment
01/05/2020

Date of final enrolment
05/02/2021

Locations

Countries of recruitment
China

Study participating centre
Shengjing Hospital of China Medical University
No. 36, Sanhao Street
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Sponsor information

Organisation
Sheng Jing Hospital

ROR
https://ror.org/0202bj006

Organisation
Shenyang Engineering Technology R&D Center of Cell Therapy Co., Ltd

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sheng Jing Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Guangwei Wang (283490189@qq.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/08/2023	02/09/2024	Yes	No