

# Effect of platelet-rich plasma gel on intrauterine adhesions

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 02/07/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/09/2024	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> 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

## Clinical Trials Information System (CTIS)

Nil known

## Protocol serial number

Nil known

# 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

## Study design

Single-center randomized study

## Primary study design

Interventional

## 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  $\geq 5$ )
2. No previous history of hysteroscopic adhesiolysis
3. Written consent obtained
4. Agreement to have second-look hysteroscopy
5. All the participants should be  $\geq 18$  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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110004

**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?
<a href="#">Results article</a>		08/08/2023	02/09/2024	Yes	No