

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Evaluation of bilateral hypogastric artery occlusion on the volume of bleeding in patients with abnormal placental adhesions

#### Protocol summary

##### Study aim

Determining the effect of bilateral hypogastric artery occlusion on the bleeding rate of patients with abnormal placental adhesion referred to Imam Sajjad Hospital, Yasuj, Iran

##### Design

A randomised clinical trial with two intervention groups, with parallel groups, without blinding, on 40 patients, and kitset.ir website was used for randomization.

##### Settings and conduct

40 patients who referred to the Women's Clinic of Imam Sajjad Hospital in Yasuj, were randomly divided into two groups without blinding: hysterectomy with bilateral hypo-gastric artery ligation and hysterectomy alone (20 patients in each group). The duration of surgery, total amount of blood loss during surgery, duration of hospitalization, need to blood products transfusion during surgery, and visceral trauma were investigated between the two groups.

##### Participants/Inclusion and exclusion criteria

Patients with abnormal placental adhesion in the form of: 1) Multiple lacunae, 2) Loss of the retro placental area, 3) Abnormalities of the serous connection of the bladder and uterus, which will be identified through trans-abdominal and trans-vaginal ultrasound by referring to a sonographer.

##### Intervention groups

The selected samples were divided into two groups of people with abnormal placental adhesion who used hypogastric artery ligation during surgery (group 1) and the group who underwent caesarean section and hysterectomy without hypogastric artery ligation (group 2).

##### Main outcome variables

The amount of bleeding during the operation; the amount of blood received; The duration of hospitalization after the operation; the duration of the operation.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230101057014N1**

Registration date: **2023-02-04, 1401/11/15**

Registration timing: **retrospective**

Last update: **2023-02-04, 1401/11/15**

Update count: **0**

##### Registration date

2023-02-04, 1401/11/15

##### Registrant information

##### Name

mehrnaz kherad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3837 0829

##### Email address

dr.mehrnaz.kherad@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-23, 1400/08/01

##### Expected recruitment end date

2022-03-21, 1401/01/01

##### Actual recruitment start date

2021-11-06, 1400/08/15

##### Actual recruitment end date

2022-08-05, 1401/05/14

##### Trial completion date

2022-08-05, 1401/05/14

##### Scientific title

Evaluation of bilateral hypogastric artery occlusion on the volume of bleeding in patients with abnormal placental adhesions

### Public title

Bilateral hypogastric artery occlusion on the volume of bleeding in patients with abnormal placental adhesion

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients with abnormal placental adhesion with Multiple Lacuna Patients with abnormal placental adhesion due to loss of the retroplacental region Patients with abnormal placental adhesion that abnormalities of the serous connection of the bladder and uterus, which will be identified through trans-abdominal and trans-vaginal ultrasonography by referring to the sonographer.

#### Exclusion criteria:

Cases that have a high risk for bleeding during surgery include bleeding disorders (such as hemoglobinopathies, and thrombocytopenia) Cases receiving anticoagulant treatment, etc Cases of abnormal invasive placenta that require quick termination of pregnancy, such as heavy bleeding in the emergency department of people who have underlying diseases such as diabetes, blood pressure disorders, heart diseases, etc. Those who refused to participate in the study

### Age

No age limit

### Gender

Female

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: **40**

Actual sample size reached: **40**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In order to randomly select the treatment method using the kitset.ir website patients were divided into two groups and placed in their own group at the beginning of the study. In this way, first a number is considered for each patient and the first and last number and the desired number of numbers are entered in the relevant part of the mentioned site and by clicking on the number generation option, the numbers are given to us selectively and randomly.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

##### Street address

Deputy of research and technology of Yasuj University of Medical Sciences, Shahid Motahari boulevard, Yasuj city, Kohgiluyeh and Boyer-Ahmad Province, Iran.

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591741417

#### Approval date

2021-10-16, 1400/07/24

#### Ethics committee reference number

IR.YUMS.REC.1400.127

## Health conditions studied

### 1

#### Description of health condition studied

Abnormal placental adhesion

#### ICD-10 code

O00.0

#### ICD-10 code description

Abdominal pregnancy

## Primary outcomes

### 1

#### Description

The amount of bleeding volume during the surgery

#### Timepoint

During the surgery

#### Method of measurement

In order to estimate the volume of blood lost during the surgery, the volume of liquid collected in the suction device, the difference in the weight of clean and soaked in blood gauze and lung gauze and the number of towels used to control the bleeding were used.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In the hypo-gastric artery ligation group, first 10 units of oxytocin are used to eutronicize the uterus, and in case of high suspicion of placental adhesion, the patient's bleeding is controlled by bilateral hypogastric artery ligation. An oncologist starts the surgery by opening the posterior peritoneum that covers the bifurcation of the common iliac vessels. Then, bilateral hypo-gastric artery ligation steps are carefully performed. Before performing this surgery and also after closing the hypogastric artery, checking the femoral pulse on both sides is done.

#### Category

Treatment - Surgery

## 2

#### Description

Intervention group: In the hypo-gastric artery group without ligation, cesarean surgery and hysterectomy are performed. The cesarean surgery starts by cutting the skin from the mid-line until exposing the uterus, and the fetus is delivered through the classical upper section. The umbilical cord is cut and closed by using a Kokher clip.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Sajad Hospital

##### Full name of responsible person

Parvin Ghaffari

##### Street address

Next to Azadi hotel, Yasuj city, Kohgiluyrh and Boyer-Ahmad province.Iran.

##### City

Yasuj

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##### Postal code

7591741417

##### Phone

+98 74 3222 0163

##### Email

Emamsajad@gmail.com

##### Web page address

<https://emamsajad.yums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Seyyed Amin Hosseini

##### Street address

Deputy of research and technology of Yasuj University of Medical Sciences, Shahid Motahari boulevard, Yasuj city, Kohgiluyeh and Boyer-Ahmad Province, Iran.

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+98 74 3333 7251

##### Email

en@yums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Yasouj University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Parvin Ghaffari

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Yasuj University of Medical Sciences, Shahid Motahari boulevard, Yasuj city, Kohgiluyeh and Boyer-Ahmad Province, Iran.

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pari.ghaffari@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Parvin Ghaffari

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Shekoofeh Nikooei

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available