

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.

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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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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Parvin Ghaffari

Position

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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

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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