

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of two methods of closing uterine vessels and using tourniquet in open myomectomy among hospitalized patients

Protocol summary

Study aim

The comparison of two methods of closing the uterine vessels and the use of tourniquets in open myomectomy among patients admitted to Imam Sajjad Hospital in Yasouj.

Design

Clinical trial with 2 intervention groups with parallel groups, without blinding, without randomization, on 60 patients.

Settings and conduct

From the patients referred to Imam Sajjad hospital clinic for surgery appointment, a number of samples are selected and after hospitalization, the types of surgery and their consequences are explained. Then, in the operating room, one of the two surgical methods is performed on them and the amount of bleeding is checked. Patients are followed up for 2 week in terms of complications.

Participants/Inclusion and exclusion criteria

No history of underlying disease, coagulation problem, malignancy, previous myomectomy surgery, drug use to reduce the volume of myoma, and patient's consent and cooperation to provide information.

Intervention groups

In the ligation group, the uterine vessels will be closed bilaterally, and in the tourniquet group, the vessels will be closed with a penrose drain around the lower uterine segment.

Main outcome variables

Measuring the amount of bleeding after 2 surgical methods and comparing them

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221208056750N1**

Registration date: **2022-12-20, 1401/09/29**

Registration timing: **prospective**

Last update: **2022-12-20, 1401/09/29**

Update count: **0**

Registration date

2022-12-20, 1401/09/29

Registrant information

Name

Parvin Ghaffari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 341 2031

Email address

pari.ghaffari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of closing uterine vessels and using tourniquet in open myomectomy among hospitalized patients

Public title

Comparison of two methods of uterine artery ligation and the use of tourniquets in open myomectomy among

patients admitted to Imam Sajjad Hospital in Yasuj, Iran

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No history of underlying disease
Absence of coagulation problem
No history of malignancy
No history of previous myomectomy surgery
No history of taking medication to reduce myoma volume
Patient consent and cooperation to provide information

Exclusion criteria:

Lack of patient consent 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: 60

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Deputy of Research and technology of Yasuj
University of Medical Sciences

Street address

Kohgiluyeh and Boyer-Ahmad Province, Yasuj, Shahid
Motahari boulevard, MHHQ+JHX

City

Yasuj

Province

Kohgilouyeh-va-Boyr Ahmad

Postal code

7591741417

Approval date

2021-10-16, 1400/07/24

Ethics committee reference number

IR.YUMS.REC.1400.125

Health conditions studied

1

Description of health condition studied

Patients with myoma in the uterus

ICD-10 code

P90-P96 Ot

ICD-10 code description

Certain conditions originating in the perinatal period

Primary outcomes

1

Description

The amount of Bleeding will be estimated according to the measurement of the weight of consumed gases, the amount of blood collected in the suction container and hemoglobin measurement, and this amount will be compared in two surgical methods.

Timepoint

Weighing the gases used during surgery and measuring the amount of blood collected in the suction container at the end - hemoglobin measurement 6 hours after the surgery

Method of measurement

Calculating the weight of completely wet gauze after surgery (about 46 grams) compared to the weight of a sterile gauze before surgery (about 6 grams) - Measuring the amount of blood collected in the suction container based on the amount of filled volume - Measuring hemoglobin 6 hours After surgery by venous blood test taken from the patient

2

Description

Investigation of possible complications and symptoms of the patient

Timepoint

Up to 2 weeks after discharge

Method of measurement

In this period, the possible symptoms and complications during the visits of the patients or the phone calls made by the patients to the given contact number are entered in the relevant checklist.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the ligation group, uterine vessels are closed bilaterally by absorbable thread near the uterus without harming the uterus.

Category

Treatment - Surgery

2

Description

Intervention group: In the tourniquet group, first a penrose drain (0.75 inch) is placed around the lower segment of the uterus, a space is created in the broad ligament at the level of the connection between the cervix and the uterus, and the penrose drain is removed from it and tied under tension with a clamp. We hold it so that the uterine and ovarian vessels are completely closed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Sajad hospital

Full name of responsible person

Parvin Ghaffari

Street address

Kohgiluyeh and Boyer-Ahmad Province, Yasuj , next to Azadi Hotel

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Phone

+98 74 3322 0163

Email

emamsajad@gmail.com

Web page address

Http://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

Kohgiluyeh and Boyer-Ahmad Province, Yasuj, Shahid Motahari boulevard, MHHQ+JHX

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Phone

+98 74 3334 6079

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

Kohgiluyeh and Boyer-Ahmad Province, Yasuj, Shahid Motahari boulevard, MHHQ+JHX

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Phone

+98 74 3333 7251

Email

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

Street address

Kohgiluyeh and Boyer-Ahmad Province, Yasuj, Shahid Motahari boulevard, MHHQ+JHX

City
Yasuj
Province
Kohgiluyeh-va-Boyrabad
Postal code
7591741417
Phone
+98 74 3333 7251
Email
pari.ghaffari@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Shiva Torki Baghbadrani
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Kohgiluyeh and Boyer-Ahmad Province, Yasuj, Shahid
Motahari boulevard, MHHQ+JHX
City
Yasuj
Province

Kohgiluyeh-va-Boyrabad
Postal code
7591741417
Phone
+98 74 3333 7251
Email
dr.sheida.torki@gmail.com

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