

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Uterine myometrial thickness at the site of myomectomy scar after laparoscopic myomectomy compared to conventional open myomectomy

Protocol summary

Study aim

Uterine myometrial thickness at the site of myomectomy scar after laparoscopic myomectomy compared to conventional open myomectomy

Design

clinical trial on 90 patients, no blinded

Settings and conduct

This study will be performed on 90 patients with uterine myomas type 2-5 with different clinical symptoms who are referred to Alzahra Hospital in Tabriz and undergo laparoscopic or laparoscopic myomectomy due to the need for surgery. Vicryl suture is used for suturing and the uterine wall is sutured in two layers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All women who undergo surgery due to having uterine type 2-5 myomas and with various clinical symptoms such as abnormal uterine hemorrhage, pain, rapid growth of myoma and compressive effects on adjacent offal. Exclusion criteria: patient dissatisfaction, single myomas greater than 8 cm and multiples greater than 5 cm, multiple myomas more than three, subserosal myomas, type 2-0 myomas, history of previous surgeries more than once, previous myomectomy history, malignancy in endometrial samples.

Intervention groups

A total of 90 patients of women with uterine myoma who need surgery for various reasons such as unbearable abdominal pain, medically resistant uterine bleeding, compressive effects on adjacent viscera, infertility or any other reason need surgery. Vicryl suture is used for suturing and the uterine wall is sutured in two layers.

Main outcome variables

Blood hemoglobin levels, Adequacy of sutures in myomectomy, bleeding during surgery, Length of hospital stay, Scar thickness of uterine myometer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211103052950N3**

Registration date: **2022-04-24, 1401/02/04**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-24, 1401/02/04**

Update count: **0**

Registration date

2022-04-24, 1401/02/04

Registrant information

Name

Fatemeh Tabatabaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3326 2754

Email address

drtabatabaeigyn@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Uterine myometrial thickness at the site of myomectomy scar after laparoscopic myomectomy compared to conventional open myomectomy

Public title
 Uterine myometrial thickness at the site of myomectomy scar

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 All women in need of surgery due to uterine type 2-5 myomas
Exclusion criteria:
 Patient dissatisfaction , Single myomas larger than 8 cm
 Multiples myomas more than three in number Multiples myomas larger than 5 cm Type 2-0 myomas More than one previous surgeries Previous myomectomy The presence of malignancy in endometrial samples. Sub-serous myomas

Age
 From 15 years old

Gender
 Female

Phase
 N/A

Groups that have been masked
 No information

Sample size
 Target sample size: 90

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

Ethics Committee Of Tabriz University Of Medical Sciences

Street address

Third Floor, Central Building Number 2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2022-04-01, 1401/01/12

Ethics committee reference number

IR.TBZMED.REC.1401.003

Health conditions studied

1

Description of health condition studied

Uterine myoma

ICD-10 code

2E86.0

ICD-10 code description

Fibromyoma of uterus

Primary outcomes

1

Description

Uterine myometrial thickness at the site of myomectomy scar

Timepoint

Four months after surgery - Eight months after surgery

Method of measurement

ultrasonographic study

Secondary outcomes

1

Description

Comparison of during of hospital stay in laparoscopic and laparotomy myectomy

Timepoint

During hospitalization after surgery

Method of measurement

according to hours of hospitalization

2

Description

Comparison of intraoperative bleeding in laparoscopic and laparotomy myectomy

Timepoint

during the hospitalization

Method of measurement

Differential hemoglobin levels before and after surgery

3

Description

Comparison of duration of operation in laparoscopic and laparotomy myomectomy

Timepoint

during the surgery

Method of measurement

Surgery time in minutes

4

Description

Comparison of the time required to achieve proper vascularity (similar to other parts of the myometrium)

and the minimum myometrial thickness of 2 mm at the site of myomectomy scar in two methods of laparoscopy and laparotomy

Timepoint

4 months and 8 months after surgery

Method of measurement

sonography

5

Description

Comparison of the number of endometrial openings during myomectomy with laparoscopic and laparotomy

Timepoint

during the surgery

Method of measurement

observing

Intervention groups

1

Description

Intervention group: Patients undergoing laparoscopic myomectomy

Category

Treatment - Surgery

2

Description

Intervention group: Patients undergoing laparotomy myomectomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Doctor فاطمه tabatabaei

Street address

South Army Street, Al-Zahra Hospital, Tabriz, East Azerbaijan Province

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Phone

+98 41 3553 9163

Email

alzahrahosp@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Parviz Shahabi

Street address

No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3335 7310

Email

research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for Research,Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Doctor fateme tabatabaei

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

South Army Street - Al-Zahra Hospital - Operating Room of Tabriz, East Azerbaijan Province

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Phone

+98 41 3476 7121

Fax

+98 41 3334 1994

Email

Dratabataeigyn@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Doctor fateme tabatabaei

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

South Army Street - Al-Zahra Hospital - Operating Room of Tabriz, East Azerbaijan Province

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Phone

+98 41 3476 7121

Fax

+98 41 3334 1994

Email

Dratabataeigyn@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Doctor fateme tabatabaei

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

South Army Street - Al-Zahra Hospital - Operating Room of Tabriz, East Azerbaijan Province

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Phone

+98 41 3476 7121

Fax

+98 41 3334 1994

Email

Dratabataeigyn@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The part of the data that is related to the main outcome of the project and the report of the results of the study will be published.

When the data will become available and for how long

One year after the publication of the project results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

In order to conduct more extensive research in this field.

From where data/document is obtainable

dr.fateme tabatabayee dratabataeigyn@gmail.com

What processes are involved for a request to access data/document

The title of the relevant research project and the reason for requesting the data should be sent via email.

Comments