

Results of using laparoscopic (keyhole) surgery to remove large fibroids (noncancerous growth of muscle tissue in the uterus) with temporary clamping of the uterine blood vessels compared to other surgical methods

Submission date 20/01/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/01/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/01/2023	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

A fibroid is a noncancerous (benign) growth of muscle tissue in the uterus. They are also known as "leiomyomas" or "myomas." They can vary in size and can be found either inside the uterus, on the outer surface of the uterus, or within the uterine wall. Some women with fibroids do not experience any symptoms, while others may experience heavy menstrual bleeding, pelvic pain and pressure, or difficulty getting pregnant.

The aim of the study is to test if different surgical techniques for fibroid removal can improve the results of infertility treatment in women of reproductive age with uterine fibroids.

Who can participate?

Women aged 25-30 years, with primary infertility and fibroids, who are planning a pregnancy.

What does the study involve?

"Laparoscopic myomectomy" is a type of surgery that uses a thin tube with a camera on the end (laparoscope) to remove fibroids (also known as "leiomyoma nodules") from the uterus.

"Temporary cross-clamping of uterine arteries" means that during the surgery, the blood flow to the uterus is temporarily stopped by clamping the arteries that supply blood to the uterus. This is done to control bleeding during the surgery.

Participants are randomly allocated to 4 groups: 1. Laparotomy myomectomy; 2. Laparoscopy without uterine artery cross-clamping; 3. Laparoscopy with uterine artery cross-clamping; 4. Resectoscopy myomectomy. Three months later, the scar was assessed and the condition of the uterine cavity during hysteroscopy. Long-term results were assessed by the number and time of pregnancy and childbirth after the operation.

What are the possible benefits and risks of participating?

The benefits of participation are the opportunity to receive highly specialized medical care and improve health.

Risks - standard surgical and anesthetic risks.

Where is the study run from?

The Institute of Reproductive Medicine (Kazakhstan)

When is the study starting and how long is it expected to run for?

March 2018 to October 2022

Who is funding the study?

The Institute of Reproductive Medicine (Kazakhstan)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Comparison of reproductive and other outcomes in laparoscopic myomectomy with temporary cross-clamping of uterine arteries for submucosal large leiomyoma nodules with other surgical techniques

Acronym

Sublapec

Study objectives

Laparoscopic myomectomy with temporary cross-clamping of uterine arteries is the best method for surgical treatment for submucosal large leiomyoma

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 28/11/2022, Ethics Commission of the Kazakhstan Medical University "Higher School of Public Health" (19A Utepov street, Almaty, Republic of Kazakhstan, +7(727) 337 80 28; ksph@ksph.kz), ref: 04-09-86719

Study design

Single-centre interventional not-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Improve treatment outcomes for women with infertility associated with uterine fibroids

Interventions

The authors randomized the participants into 4 groups. Each of the participants was given an envelope with the number of the group generated by a computer:

1. Laparotomy myomectomy;
2. Laparoscopy without uterine artery cross-clamping;
3. Laparoscopy with uterine artery cross-clamping;
4. Resectoscopy myomectomy.

The main researcher knew about the allocation of the study groups.

Three months later, the scar was assessed and the condition of the uterine cavity during hysteroscopy. Long-term results were assessed by the number and time of pregnancy and childbirth after the operation.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Hemoglobin level is measured using general blood analysis at the initial visit, before and after the operation.
2. Blood loss is measured using blood control system during the operation.
3. Intrauterine pathology is measured using hysteroscopy 3 months after the operation.

Secondary outcome measures

Diagnostic hysteroscopy was performed 3 months after the operation and every 6 months after hysteroscopic control for 2 years. The questions concerned only the following: the onset of spontaneous pregnancy, gestational age and outcome of pregnancy.

Overall study start date

01/03/2018

Completion date

01/10/2022

Eligibility

Key inclusion criteria

1. Age from 25 to 30 years;
2. Presence of one 4–6 cm myoma nodule according to expert ultrasound;
3. Anti-Mullerian hormone (AMH) level not less than 2 ng/ml;
4. Confirmed patency of both uterine tubes;
5. Confirmed absence of other forms of infertility;
6. Primary infertility;
7. Patients planning spontaneous pregnancy

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

160 participants, divided into 4 groups of 40 people

Total final enrolment

160

Key exclusion criteria

1. Acute or chronic inflammatory and infectious diseases during exacerbation;
2. Malignant neoplasms;
3. Benign neoplasms of the ovaries and/or uterus;
4. Hemorrhoids of stage 3 or 4;
5. Uncompensated chronic somatic diseases;
6. Thromboses;
7. Hemoglobin level of less than 100 g/l for groups 1;2;4; for group 3 it is less than 90 g/l;
8. Non-compliance with the inclusion criteria.

Date of first enrolment

01/07/2018

Date of final enrolment

01/07/2022

Locations**Countries of recruitment**

Kazakhstan

Study participating centre**Institute of Reproductive medicine**

99 Tole bi street

Almaty

Kazakhstan

050009

Sponsor information**Organisation**

Institute of Reproductive Medicine Almaty

Sponsor details

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Institute of reproductive medicine Almaty

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/03/2023

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			23/01/2023	No	Yes
Protocol file			23/01/2023	No	No