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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

Registration date
25/01/2023

Overall study status
Completed

Last Edited
23/01/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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-blunded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))

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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Institute of reproductive medicine Almaty

Results and Publications

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