Informed consent to participate in the study.

Study leader

Responsible for the study, doctoral student, obstetrician-gynecologist - surgeon Barmanasheva Zauresh Yertiskyzy

Scientific consultant - d.m.s. Kotlobovsky V.I., MD Kudaibergenov T.K.

Title of the study: "Modern surgical tactics in the treatment of infertility in combination with uterine myoma"

Duration: 01.12.2021 - 01.01.2024

Estimated number of participants: 160 people

Contacts (position, category of contact person, phone numbers)

Barmanasheva Zauresh Yertiskyzy - doctoral student, obstetrician-gynecologist - surgeon

in LLP "Institute of Reproductive Medicine" - 87014029691; Call Center – 8771 9343434

Purpose of the study: to improve the results of infertility treatment in women with uterine myoma, which deforms its cavity, by laparoscopic myomectomy with temporary occlusion of the uterine arteries.

Study information:

The prevalence, steady increase in the frequency and "rejuvenation" of uterine fibroids, which entail a decrease in the reproductive function of women, dissatisfaction with the results of treatment, determine the relevance and prospects of research on this issue [1,3,5,7,9,13].

In the population, the frequency of uterine fibroids in women with infertility varies from 44 to 70%. At present, the introduction of new technologies has made it possible to expand the indications for organ-preserving surgical benefits aimed at preserving the reproductive function of women, leaving behind them the right and opportunity to become a mother [1,2,6,8,10,11]. At the same time, laparoscopic surgery remains the main option for surgical treatment of patients with uterine myoma, and the use of techniques that provide transient uterine ischemia reduces the risk of intraoperative blood loss and provides optimal conditions for performing the operation [2,5,7,12,13].

In the treatment of gynecological pathologies such as uterine fibroids, surgical intervention remains a priority method [3,4,5]. Given the achievements of modern medicine, the range of possible combinations is expanding when choosing the optimal strategy and tactics of therapy, and the integration of innovative endoscopic treatment becomes natural [10,11].

It should be noted that surgery remains the main treatment for uterine fibroids [12,15]. Quite often, a hysterectomy is performed, which is a demonstration of the impotence of modern medicine in the treatment of these diseases, since it leads to the loss of reproductive function, excluding the possibility of having children, and reduces the quality of life of a woman [1,8]. Therefore,

hysterectomy has become limited to situations where there is no need to preserve fertility, when it is impossible to perform an organ-preserving operation. Accordingly, against the background of the introduction of new technologies, organ-preserving tactics have become a priority in the surgical treatment of this pathological condition [11,12]. To reduce the volume of intraoperative blood loss during laparoscopic myomectomy of large nodes, technologies for performing the operation against the background of transient uterine ischemia began to be used, and hysteroresectoscopy is used to remove submucosal nodes. To do this, clamps are applied to the internal iliac or uterine arteries, which ensures that myomectomy is performed on a “dry organ” [4,6].

Methods of surgical treatment of the disease are the subject of controversy and discussion. Hysterectomy cannot be performed in patients who wish to achieve reproductive function or preserve the uterus in the presence of large interstitial-submucosal nodes. Conducting organ-preserving operations with such an arrangement of nodes is everywhere accompanied by profuse bleeding, difficulty in performing operations, hysterectomy and failure of the scar on the uterus.

For the study, 160 case histories of patients admitted to the hospital of the Institute of Reproductive Medicine LLP with a diagnosis of infertility in combination with uterine fibroids larger than 4 cm, types 0,1,2,3 according to FIGO will be studied. The operations were carried out between January 2015 and September 2022. All patients will be divided into 4 groups:

Group 1 - patients who underwent laparotomy myomectomy,

Group 2 - patients who underwent laparoscopic myomectomy,

group 3 - patients who underwent laparoscopic myomectomy using the method of temporary occlusion of the uterine arteries,

Group 4 - patients who underwent myomectomy by hysteroresectoscopy.

To control the quality of the operation, the number of reoperations, complications and the implementation of the reproductive function, all patients were invited to a follow-up examination to collect and record data from September 2021 to September 2022.

The collection of data is strictly anonymous to avoid the risk of disseminating health information.

Study procedures (what will be required of the participant).

1. Come to the gynecological examination on the appointed day and hour

2. Answer the doctor's questions, which will be entered in the table

3. In case of non-appearance for examination, inability or unwillingness to continue participation in the study, please report using the contacts provided above.

Risks/Discomfort. There is no risk to your health or condition during a follow-up appointment with a doctor, since no invasive and laboratory diagnostic procedures are included in the scope of the study. The risks associated with surgery are specified in the informed consent signed before surgery.

Benefit (direct, social)

Social benefit:

Based on the data obtained, gynecologists-surgeons of gynecological hospitals will be offered a new method of surgical treatment of uterine fibroids with a deformation of its cavity larger than 4 cm. as a result, the chances of preserving the organ and the reproductive function of a woman will increase.

Direct benefit.

For study participants, the benefit is close, free monitoring of their condition after surgery for 5 years.

Confidentiality. When processing patient data, all passport data are coded by groups, all data on operations and postoperative treatment are anonymous.

Compensation. Monetary compensation is not provided, however, you get the opportunity to monitor your condition for free and receive recommendations from a gynecologist.

Voluntary participation. You do not have to agree to participate in the study, and you can change your mind at any time.

Confirmation of consent

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Contact information for questions or complaints from the local ethics committee, principal investigator:

Barmanasheva Zauresh Yertiskyzy - doctoral student, obstetrician-gynecologist - surgeon

in LLP "Institute of Reproductive Medicine" - 87014029691; e-mail: zaurew9@gmail.com

Signature ¬¬¬_____

Study Coordinator

Name Barmanasheva Z.E. Signature…… Date……

Study participant

Name…….. Signature…….. Date……