ISRCTN23741622 https://doi.org/10.1186/ISRCTN23741622

Relapse prophylaxis and early recognition of pelvic organ prolapse in primary medical care organizations

Submission date
17/01/2023

Recruitment status
No longer recruiting

Registration date
30/01/2023

Overall study status
Completed

Last Edited
14/03/2023

Condition category
Nervous System 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
It is necessary to develop a tactic for pelvic floor rehabilitation, given the high frequency of operations for genital prolapse in women, the frequency of relapses and the lack of clear recommendations for postoperative management. This study will research a course of pelvic floor muscle training after pelvic prolapse surgery with the aim of improving pelvic floor muscle contraction strength, and preventing the recurrence of pelvic prolapse. The strength of muscle contractions of the pelvic floor muscles may serve as a prognostic identifier for a possible recurrence of pelvic prolapse.

Who can participate?
Patients with grade II anterior and posterior vaginal wall prolapse and grade III stress urinary incontinence

What does the study involve?
Patients in both groups will receive surgical treatment. In the treatment group, 2 months after the operation, the patients will undergo a 6-month course of training for the pelvic floor to assess the effect of such a scheme on the strength of muscle contractions and determine the threshold value of muscle strength for predicting relapse in primary medical care organizations.

What are the possible benefits and risks of participating?
Operative treatment carries the risks of complications, however, it is carried out in accordance with the protocol for the diagnosis and treatment of genital prolapse of the Republic of Kazakhstan, and the operating doctor is responsible for the complications of surgical treatment on the basis of the contract. Surgical treatment is not a new method or our development. Our suggestion to do the exercises for 6 months would probably cause pelvic pain or discomfort. However, to avoid risks, we started the exercises 2 months after the operation, when we found complete healing of the vaginal tissue. There were no unwanted effects. The scheme of exercises was not exhausting and was simple to follow.

Where is the study run from?
Kazakhstan Medical University (Kazakhstan)

When is the study starting and how long is it expected to run for?
February 2021 to July 2022

Who is funding the study?
Kazakhstan Medical University (Kazakhstan)

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Optimization of the surgical treatment of genital prolapse

Acronym
POPRP

Study objectives
1. Pelvic floor muscle training after pelvic prolapse surgery improves pelvic floor muscle contraction strength
2. Pelvic floor muscle training after surgical treatment after pelvic prolapse surgery serves to prevent the recurrence of pelvic prolapse

3. The strength of muscle contractions of the pelvic floor muscles serves as a prognostic identifier for a possible recurrence of pelvic prolapse

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/01/2021: Bioethics committee 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: 132/4

Primary study design
Interventional

Study design
Randomized controlled single-blind study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of recurrence of genital prolapse after surgical treatment

Interventions
The study aims to prevent the recurrence of genital prolapse after surgical treatment (anterior and posterior colpotomy, colporrhaphy with perineal levatorplasty) using a combination of a 6-month course of training for the pelvic floor muscles.

The authors will randomly divide the participants into two groups. Each participant receives an envelope with the number of the group they would be assigned to. The chief investigator knows which group patients are assigned to, whereas the participants are blinded to which group they were assigned to. Participants were divided into 2 groups: the treatment group (30 patients) and the control group (30 patients). The participants will complete a study program and a follow-up examination. Compliance is continuously controlled by gynaecologists in an online regimen. Exercises are expected to be comfortable to perform during the everyday routine and not be exhausting.

Procedure
The patients in both groups underwent surgical treatment such as anterior and posterior colpotomy, colporrhaphy with perineal levatorplasty. These surgical methods are included in Kazakhstan's clinical protocol for the diagnosis and treatment of female genital prolapse. The patients in the treatment group started the pelvic floor muscle training program 2 months after surgery and continued the program for 6 months. The patients in the control group followed conventional recommendations for 2 months (6-8 weeks) - the required amount of time when the sutures (Vikryl) dissolve completely, pelvic pain disappears and the patients feel completely normal. Physical activity is not recommended until complete healing (6-8 weeks), as it may cause pain or interfere with the healing process. Before training, all patients will be given instructions on the structure of pelvic floor muscles, their function, the importance of training and training techniques, as well as which muscles we work on during training. All patients will be trained in how to perform pelvic floor exercises during their visit to the gynecologist.

Training program:
First week: 3 rounds of 10 contractions of the pelvic floor muscles (hold 3 seconds) and 3 rounds of 5 contractions (hold 12 seconds) per session, twice a day every other day; from the second week to the 12th week: 3 rounds of 20 contractions of the pelvic floor muscles (hold for 3 seconds) and 3 rounds of 10 contractions (hold for 12 seconds) per session, twice a day every other day; from weeks 13 to 24: 3 rounds of 20 contractions of the pelvic floor muscles (hold for 3 seconds) and 3 rounds of 10 contractions (hold for 12 seconds) per session, twice a day every day.

All patients were divided between 6 gynaecologists in primary medical care organizations who controlled the compliance of patients to prescribed recommendations and training with an online monitoring system using available messengers.

Intervention Type
Mixed

Primary outcome(s)
Presence of anatomical prolapse measured during gynecological examination using POP-Q international scale for the estimation of prolapse stage prior to treatment and 8 months after surgical operation

Key secondary outcome(s)
Helath-related quality of life measured using the Prolapse Quality of Life Questionnaire (P-QoL) in Russian and Kazakh languages prior to treatment and 8 months after treatment.

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. Anterior and posterior vaginal wall prolapse stage II, according to the Pelvic Organ Prolapse Quantification System (POP-Q) classification and stress-induced urinary incontinence stage III, which was determined by the classification of D.V. Kahn
2. Aged 45 years old and under
3. History of two or more labours
4. No consent for conservative treatment
5. No consent for use of vaginal synthetic prostheses, including urethral sling
6. No history of conservative treatment of prolapse, including pelvic floor muscles training
7. No history of metabolic diseases (diabetes mellitus, obesity, metabolic syndrome, thyroid gland disorders, calcium phosphate metabolism disorders)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
60

Key exclusion criteria
1. Urgent or combined urinary incontinence
2. Contraindications to surgical treatment and anaesthesia (general and regional anaesthesia: spinal, epidural anaesthesia)
3. Acute or chronic inflammatory diseases, acute phase of infectious diseases, malignant tumours, anaemia, benign ovarian and/or uterine tumours, pregnancy, haemorrhoids stage 3 and 4, decompensated chronic diseases, thrombosis and multiple drug allergies

Date of first enrolment
01/08/2021

Date of final enrolment
01/10/2021

Locations

Countries of recruitment
Kazakhstan

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LS Clinic
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Sponsor information

Organisation
Kazakhstan Medical University

ROR
https://ror.org/034p3rp25

Funder(s)

Funder type

University/education

Funder Name
Kazakhstan Medical University

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to a lack of participant consent to share data. All data will be in a non-public Excel database, strictly anonymously. All the participants signed the informed consent prior to be enrolled in a study. This complies with the requirements for clinical trials, which are conducted at the initiative of the author. Registration of the study is carried out in the research base of the university on behalf of which the study is being conducted.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			30/01/2023	No	No