Trials

STUDY PROTOCOL

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The influence of simultaneous posterior colporrhaphy and perineoplasty on the efficiency and safety of mesh-augmented sacrospinal fixation (apical sling) in advanced POP repair

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Abstract

Background Pelvic organ prolapse (POP) is one of the most common pathologies of the pelvic floor, and it can be found among 40–60% of women who have given birth. Correction of the defect of the DeLancey level II without reconstruction of the apical defect is doomed to failure. Also, in the structure of pelvic floor defects, there is often an incompetency of the perineal body, as a consequence of traumatic delivery. Perineoplasty is considered to be the main method of correction for perineal body incompetency. However, it is worth mentioning that there are no randomized trials, which estimate the influence of simultaneous correction of the perineal body on the effectiveness of transvaginal apical fixation.

Methods It is planned to include 310 patients in this trial. Patients who met the inclusion/exclusion criteria will be randomized into 2 groups: 1st group—patients who will undergo mesh-augmented sacrospinal fixation with anterior and posterior colporrhaphy without perineoplasty, 2nd group—patients who will undergo mesh-augmented sacrospinal fixation with anterior and posterior colporrhaphy and perineoplasty. Patients will be called to an appointment 6, 12, and 24 months after discharge.

Discussion The aim of this trial is to evaluate the efficiency and safety of simultaneous perineoplasty on the clinical and anatomical efficacy of mesh-augmented sacrospinal fixation in advanced pelvic organ prolapse repair. Based on previous studies, it was difficult to estimate and comprehend whether colpoperinoplasty actually reduces the risk of prolapse recurrence.

Trial registration NCT05422209. Registered on 18 May 2022.

Keywords Pelvic organ prolapse, Vaginal repair, Vaginal mesh, Sacrospinous fixation, Colporrhaphy, Perineoplasty

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Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title {1}	The Influence of Simultaneous Posterior Colporrhaphy and Perineoplasty on the Efficiency and Safety of Mesh-augmented Sacrospinal Fixation (Apical Sling) in Advanced POP Repair.
Trial registration {2a and 2b}.	First version of the study is registered in United States National Library of Medicine [https://clinicaltrials.gov] NCT05422209 from 18.05.2022
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Name and contact information for the trial sponsor {5b}	Trial Sponsor: SPBSU (St. Petersburg State University Hospital) Address: Saint-Petersburg, Fontanka Embankment 154 Telephone: +7(812) 676-25-25 Email: 6762525@gosmed.ru
Role of sponsor {5c}	The sponsor played no part in study design, collection, management, analysis, and interpretation of data, writing of the report. The sponsor did not contribute to the decision to submit the report for publication.

Introduction

Background and rationale {6a}

Pelvic organ prolapse (POP) is one of the most common pathologies of the pelvic floor, and it can be found among 40–60% of women who have given birth [1, 2]. It is known that POP in most cases is caused by a combined anatomical defect of the pelvic floor. The most common one is anterior apical prolapse [3]. Today, the vast majority of specialists agree on the key role of apical support. Correction of the defect of the DeLancey level II without reconstruction of the apical defect is doomed to failure [3, 4]. Also, in the structure of pelvic floor defects, there is often an incompetency of the perineal body, as a consequence of traumatic delivery. The perineal body is considered to be a part of the III level of vaginal support by DeLancey [5]. It is known that damage to the perineal body as well as the increase of the hiatus can lead to the development or progression of the POP, due to the incompetency of the structures, that were supposed to be reliable enough for pelvic floor organs.

Perineoplasty is considered to be the main method of correction for perineal body incompetency. Not only this procedure has good cosmetic result (prevents gaping of the hiatus and minimizes scaring), but also keeps all muscular-fascial structures of the pelvic floor as anatomically correct as possible [6, 7]. However, it is worth mentioning that there are no randomized trials, which estimate the influence of simultaneous correction of the perineal body on the effectiveness of transvaginal apical fixation [8]. This publication is a randomized controlled trial registered on https://clinicaltrials.gov.

Objectives {7}

To evaluate the effect of simultaneous perineoplasty on the clinical and anatomical efficiency of pelvic floor reconstruction.

Trial design {8}

Randomized controlled trial. Duration: 2 years from the end of the recruitment of patients. An Internet resource will be used for randomization https://www.sealedenvelope.com/simple-randomiser/v1/lists with the usage of the block randomization method with the size: 1 block–4 patients. We consciously chose not to make the trial "blind" because of the impossibility to hide operative methods from patients and medical personnel. However, the doctor who is in charge of collecting the data and examining patients 6, 12, and 24 months after the operation would not know in which group the patient was sorted into (Fig. 1).

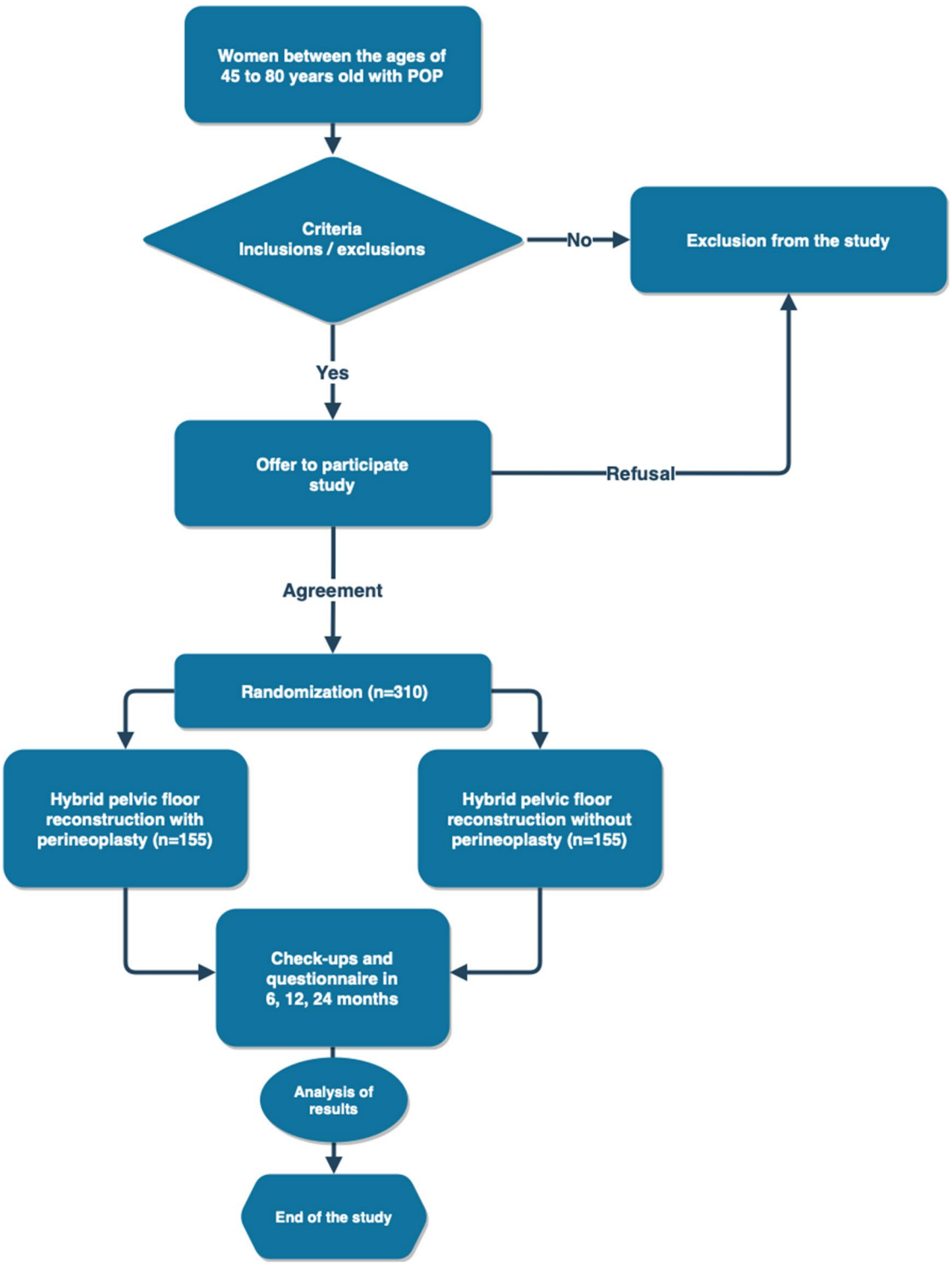

Fig. 1 Study design

Methods: participants, interventions, and outcomes

Study setting {9}

The study will be conducted on the basis of the St. Petersburg State University Hospital located in Russia, St. Petersburg, Fontanka River Embankment, 154.

Eligibility criteria {10}

It is planned to include 310 adult patients who need surgical treatment. No less than one day before the operation, the patient will be interviewed, and, if the agreement is met, an informed consent will be signed. Based on preliminary calculations (12 patients per week in the study), it will take approximately 8 months to complete the recruitment.

Who will take informed consent? {26a}

All patients participating in this trial will sign an informed consent obtained by the doctor in charge of their case.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

All patients participating in this trial will also sign an additional informed consent for the collection and use of their data, which obtained by the doctor in charge of their case.

Inclusion criteria

1. Age between 45 and 80 years;
2. The prolapse leading point is at the level of the hymenal ring or distal (Ba, $C \geq 0$ POP-Q);
3. Patient's ability to read and sign the informed consent form;
4. A socialized patient who is able to complete validated questionnaires and come to follow-up postoperative examination in the future;
5. Consent of the patient to participate in the study.

Exclusion criteria

1. The presence of an oncological disease that has been diagnosed previously or is currently active;
2. Previous POP surgery, SUI, or hysterectomy
3. Existing concomitant gynecological diseases (recurrent uterine bleeding, endometrial hyperplasia, the presence of atypical cells in cervical smears, adenomyosis, multiple uterine fibroids);
4. Existing urinary incontinence;
5. Planned pregnancy
6. Active urinary tract infection or skin infection at the surgical site or acute infectious disease;
7. Inability to attend postoperative checkups;
8. Refusal to participate;
9. Bp > C in POP-Q;
10. Gh < 4 cm or > 6 cm in POP-Q.

Case management protocol

Patients who meet the inclusion/exclusion criteria in the period prior to hospitalization will be screened in full.

Interventions

Explanation of the choice of comparators {6b}

The is an opinion, which is based on very few researches, that prolapse in the anterior, apical, and posterior compartment reconstruction of I and II level by DeLancey should be accompanied by reconstruction of the perineal body (which is in the III level) in order to prevent the recurrence of pelvic organ prolapse in the future [9, 10]. However, there is not enough evidence to prove that opinion. The aim of this trial is to evaluate the efficiency and safety of simultaneous perineoplasty on the clinical and anatomical efficacy of mesh-augmented sacrospinal fixation in advanced pelvic organ prolapse repair. Based on previous studies, it was difficult to estimate and comprehend whether colpoperinoplasty actually reduces the risk of prolapse recurrence.

We chose the following lines of comparison:

1. Mesh-augmented sacrospinal fixation with posterior colporrhaphy (Hybrid pelvic floor reconstruction) and perineoplasty
2. Mesh-augmented sacrospinal fixation with posterior colporrhaphy (Hybrid pelvic floor reconstruction)

Intervention description {11a}

Patients who met the inclusion/exclusion criteria will be randomized into 2 groups:

> 1st group—patients who will undergo pelvic floor reconstruction (unilateral sacrospinal fixation using a mesh implant, anterior subfascial colporrhaphy, posterior subfascial colporrhaphy).

Description of the method: in the lithotomy position, after preparation of the surgical field and installing a urethral catheter, hydropreparation of the anterior wall of the vagina is performed with saline. A median incision is made in the anterior wall of the vagina, dissection of the paravaginal tissues in the direction of the left or right

sacrospinous ligament. The endoprosthesis "Urosling 1" © (Lintex, St. Petersburg) is passed through the sacrospinous ligament using the Urofix PL instrument using the "inside-out" technique, fixed to the fibrous ring of the cervix with interrupted sutures using Ftorex suture (USP 2). Hemostasis and the integrity of the rectum and bladder are monitored. To correct a defect in the pubocervical fascia, anterior subfascial colporrhaphy is performed with a PGA corset suture (USP 2). Then a suture on the wound of the anterior wall of the vagina is applied using PGA (USP 0). After hydropreparation of the posterior vaginal wall with saline, a median incision is made in the posterior vaginal wall, subfascial dissection of the paravaginal tissues, then posterior subfascial colporrhaphy with a PGA corset suture (USP 2). Then a suture on the wound of the posterior wall of the vagina is applied using PGA (USP 0) [11]. A distinctive feature of surgery in this group is the absence of reconstruction of the perineal body and paravaginal tissues below the level of the hymenal ring.

2nd group—patients who will undergo pelvic floor reconstruction (unilateral sacrospinal fixation using a mesh implant, anterior subfascial colporrhaphy, posterior extended subfascial colpoperineoplasty).

Description of the method: reconstruction of the anterior and apical defects of the pelvic floor support is identical to the surgical technique in the first group. The difference in the reconstruction technique of the posterior compartment lies in the fact that the median incision of the posterior wall of the vagina, dissection of the paravaginal tissues is made to the level of the posterior commissure of the vagina with the transition of the dissection to the perineal body. In order to correct a defect in the recto-vaginal fascia and the tendon center of the perineal body, posterior subfascial colporrhaphy is performed with a corset suture to the level of the posterior commissure of the vagina with the transition of a continuous suture to the perineal body. After that simple sutures are applied to the perineal body with PGA (USP 2), suture on the posterior wall and 3rd row of sutures on the perineal body are applied using PGA (USP 0). For the skin, we use simple sutures PGA (USP 3/0) [11].

For both groups, the chosen method of anesthesia is endotracheal anesthesia. The urinary catheter and tampon with Levomekol ointment, installed after the operation, will be removed the next morning. Urinary control will be carried out 2, 4, 6, and 12 h after the removal of the urethral catheter). The criterion for the recovery of urination will be the volume of residual urine less than 50 ml, according to ultrasound. If urination is not restored, the patient will be discharged with a urinary catheter under the supervision of a urologist at the place of residence. To exclude formed hematomas in the area of operation, an ultrasound examination of the pelvic organs will be performed the next day.

Criteria for discontinuing or modifying allocated interventions {11b}

Drug dose change in response to the participant's request.

Strategies to improve adherence to interventions {11c}

Drug tablet return.

Relevant concomitant care permitted or prohibited during the trial {11d}

All patients will be given antibacterial prophylaxis before surgery, prevention of thromboembolic complications in the form of the mandatory use of compression stockings, and the appointment of low molecular weight heparins.

Table 1 Description

Description	*Inclusion in the study*	*Operation*	*Examination*	6 months	*12 months*	*24 months*
Demographics	x					
Consultation Urogynecologist/surgeon	x		x			
Consultation outpatient urogynecologist				x	x	x
Consultation with a therapist	x		x			
Consultation of other specialists	x					
Complete clinical examination	x					
Compliance with inclusion/exclusion criteria	x					
Intervention according to randomized group		x				
Questionnaires (PFDI-20, PFIQ-7, PISQ-12)	x			x	x	x
POP-Q	x		x	x	x	x
Postoperative examination			x	x	x	x

To relieve pain after surgery, nonsteroidal anti-inflammatory drugs will be prescribed, and if they are ineffective, opioid analgesics will be prescribed.

At the outpatient stage of rehabilitation, patients will be allowed to sit, but a strict restriction of physical activity and abstinence from sexual activity for 2 months is recommended.

Provisions for post-trial care {30}

Not applicable; no post-trial care is used in this trial.

Outcomes {12}

Primary clinical endpoint

1. Objective cure rate

The patient will be considered cured if, during postoperative follow-up, there is no recurrence of POP requiring repeated surgical treatment, an objective criterion is assessed according to the POP-Q classification (0–1 stage).

Secondary clinical endpoints

1. Surgery satisfaction

Will be estimated with the "Global Impression of Improvement questionnaire" (PGI-I), validated in Russia. The patient marks the number that best describes her post-operative condition, compared with how it was before surgery. The score ranges from 1 (very much better) to 7 (very much worse).

2. Influence of operation on sexual function.

Will be estimated with the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12), validated in Russia.

3. Influence of operation on the quality of life.

Will be estimated with Pelvic Floor Disability Index (PFDI-20), validated in Russia.

4. Complications

The presence of any complications, such as bleeding requiring blood transfusion, hematoma requiring drainage, organ perforation, nerve damage, accompanied by corresponding clinical manifestations, cicatricial deformity, shortening of the vagina, wound infection, urinary tract infection, chronic pelvic pain, extrusion of the implant into the vagina, urethral implant erosion, de novo dyspareunia, de novo urgency, bladder atony, and stress incontinence of urine de novo.

Factors, baseline values, and parameters that may affect the course of the postoperative period will also be assessed, such as duration of symptoms, medical history, body mass index, smoking, pre- or post-menopausal status, use of estrogen or hormone replacement therapy, repeat surgery for POP or stress urinary incontinence, and the use of a pessary (Table 1).

Participant timeline {13}

Patients will be called to an appointment 6, 12, and 24 months after discharge, they will be examined and phoned for information about the long-term period.

Completion date: within 24 months after selection.

Sample size and {14}

Taking into account the available data on the recurrence rate of unilateral sacrospinous fixation using this technology (7.4%) [11], as well as clinical observations on the recurrence rate of three-level reconstruction (1%), study power 80%, and significance level 5%, 282 patients are needed to confirm the expected difference in recurrence rate. To compensate for data loss, the estimated sample size is increased by 10%. As a result, the total sample size is 310 patients.

Recruitment {15}

In SPBSU It is estimated that 2000 patients with POP are seen each year, while a smaller number become inactive due to relocation, change of health care provider, etc. Once identified in the center, patients potentially eligible for a specific study are contacted by the nurse coordinator who explains the study and ascertains the patient's interest. If interested, the patient is seen by a urologist in the center and recommended for a trial if eligible.

Exclusion criteria

Patients who will no attend a follow-up visit within 2 months of the scheduled date and who will not answer the phone will be excluded from the study, as well as patients with a newly diagnosed cancer, decompensation of a chronic disease that may affect the study, as well as patients who die in the duration of observation.

Sequence generation {16a}

An Internet resource will be used for randomization https://www.sealedenvelope.com/simple-randomiser/v1/

lists with the usage of the block randomization method with the size: 1 block–4 patients.

Participants will be randomly assigned to either control or experimental group with a 1:1 allocation as per a computer-generated randomization.

Concealment mechanism {16b}

We consciously chose not to make the trial "blind" because of the impossibility to hide operative methods from patients and medical personnel. However, the doctor who is in charge of collecting the data and examining patients 6, 12, and 24 months after the operation would not know in which group the patient was sorted into.

Implementation {16c}

All patients who give consent for participation and who fulfill the inclusion criteria will be randomized. Randomization will be requested by the staff member responsible for recruitment and clinical interviews from the coordinating center. After that, the patient will be randomized by the staff member using the internet resource https://www.sealedenvelope.com/simple-randomiser/v1/lists. Participants will be randomly assigned to either the control or experimental group with a 1:1 allocation as per a computer-generated randomization. The urologist in charge of postoperative interviews would not know in which group the patient was sorted into.

Who will be blinded {17a}

Not applicable; no blinding was used in this trial.

Table 3 Trial characteristics

Characteristic	*Value*
Duration of study, months	32
Minimum number of patients included	282
Number of patients including losses	310
Percentage of loss compensation	10%
Bilateral Importance Index	0.05
Number of patients in a separate group	155
Time of enrollment of patients in the study, months	8
Duration of observation, months	24
Estimated time for patient recruitment, months	13

Procedure for unblinding if needed {17b}

The design is open-label with only outcome assessors being blinded so unblinding will not occur.

Plans for assessment and collection of outcomes {18a}

The initial data will contain demographic characteristics (age, sex, body mass index), in addition, patients at the prehospital stage will be asked to complete a survey using standard questionnaires validated in the Russian Federation: Pelvic Floor Disability Index (PFDI-20), Patient's Global Impressions of Improvement (PGI-I), Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-12) [12, 13].

All communication including protocol modifications will be conducted by the corresponding author.

Plans to promote participant retention and complete follow-up {18b}

Once a patient is enrolled in this trial and randomized, the study site will make every reasonable effort to follow

Table 2 Trial design

	Enrolment	**Allocation**	**Close-out**			
Timepoint	$-t_1$	**0**	***Day after operation***	***6 months***	***12***	***24***
Enrolment:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
Interventions:						
[Intervention A]				X	X	X
[Intervention B]				X	X	X
Assessments:						
Questionnaires (PFDI-20, PFIQ-7, PISQ-12)]	X			X	X	X
POP-Q	X		X	X	X	X
Examination			X	X	X	X

the patient for the entire study period. It is projected that the rate of loss-to-follow-up on an annual basis will be at most 10%. Study site staff are responsible for developing and implementing local standard operating procedures to achieve this level of follow-up.

Data management {19}

All data will be collected by staff not involved in patient care. Base, procedural, and intraoperative data will be prospectively collected and reported in the form of a patient report. Everything will be stored electronically (database) using appropriate software. Original study forms will be entered and kept on file at SPBSU.

Confidentiality {27}

Patients will be identified in the database using a unique code obtained after enrollment in the study. Patient reporting forms will only be in the form of initials and date of birth. Informed consent and contact details (for a 30-day follow-up telephone contact) will be kept separate from other records containing medical or other personal information.

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable, no biological specimens are going to be used in this trial (Table 2).

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Taking into account the available data on the recurrence rate of unilateral sacrospinous fixation using technology (7.4%) [11], as well as clinical observations on the recurrence rate of three-level reconstruction (1%), study power 80%, and significance level 5%, 282 patients are needed to confirm the expected difference in recurrence rate. To compensate for data loss, the estimated sample size is increased by 10%. As a result, the total sample size is 310 patients. The expected duration of the study is 24 months. Categorical variables will be specified as absolute numbers and percentages. To assess the change in categorical variables, Pearson's chi-square test will be used, if the assumptions are not met, Fisher's exact test will be used. Continuous variables will be displayed as mean ± standard deviation or median and interquartile range. To assess the change in quantitative variables, the Mann-Whitney test for independent groups and the Wilcoxon test for dependent groups will be used. Missing data will not be entered. The Bilateral Importance Index will be set at 0.05. All analyses will be performed using software R (R Core Team 2021).

Interim analyses {21b}

We have no plans to conduct any interim analyses since both interventions are associated with a low degree of risk.

Methods for additional analyses (e.g., subgroup analyses) {20b}

Not applicable as no additional analyses will be used in this trial.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

To compensate for data loss, the estimated sample size is increased by 10%. As a result, the total sample size is 310 patients.

Plans to give access to the full protocol, participant-level data, and statistical code {31c}

Full access protocol would be granted in the *TRIALS* journal (Table 3).

Oversight and monitoring

Composition of the coordinating center and trial steering committee{5d}

Principal Investigator (PI) and Research Physician

The role and responsibilities are as follows:

a. Preparation of protocol and revisions
b. Preparation of *Case Report Forms*
c. Organizing steering committee meetings
d. Managing CTO [*Clinical Trials Office*]
e. Publication of study reports
f. Membership in TMC [*Trial Management Committee*]

The PI and dedicated research staff (the coauthors) will form the Trial Steering Committee.

Steering committee (SC)

See the title page for the members.

The role and responsibilities of SC are as follows:

Agreement of final protocol
All lead investigators will be steering committee members
Recruitment of patients
Reviewing progress of study and if necessary agreeing changes to the protocol and/or investigators brochure to facilitate the smooth running of the study

Study planning
Responsible for trial master file
Budget administration and contractual issues with individual centers
Advice for lead investigators
Audit of 6, 12, and 24 postoperative feedback forms and decide when the site visit is to occur
Assistance with international review, board/independent ethics committee applications
Data verification
Randomization
Organization of central serum sample collection

Data manager

The data manager is responsible for the following:

Maintenance of trial data collection and data entry
Data verification

Lead investigators

The lead investigator will be identified, to be responsible for the identification, recruitment, data collection, and completion of CRFs, along with follow-up of study patients and adherence to study protocol. Lead investigators will be SC members.

The study governance for this single-site study is divided into several teams, including the oversight team, recruitment team, intervention deployment and assessment team, data management, and analysis team. The oversight team, led by the PI, has overall responsibility for the conduct and progress of the study. Each team is led by a dedicated research staff or clinician and works closely with the oversight team to establish and monitor standard operating procedures. Each team meets once in 2 weeks with the PI to discuss decisions and progress within their specific area of responsibility. Full study meetings are held every 3 months and as needed to ensure all aspects of the study are coordinated and progressing according to plan.

Composition of the data monitoring committee, its role and reporting structure {21a}

Data monitoring committee is presented by staff not involved in patient care; furthermore, we consider our trial as one with minimal risks, and thus, no external data monitoring is necessary.

Adverse event reporting and harms {22}

Given the interventional nature of the study, the risks of participating in it are due to the surgical procedure itself, regardless of participation in the study. Serious adverse complications are defined as any event that may result in death, disability, hospitalization, or prolongation of hospital stay. Investigators should make every effort to report each complication encountered and evaluate its relationship to the ongoing study. The link between the study and possible severe complications should be described using the following categories: unanticipated, unrelated, probably not related, likely related, and related. The ethics committee should be notified of all serious complications.

As recommended, complications that are due to the natural course of the disease/progression of the primary disease process or expected complications of a critical illness should not be reported as a severe complication unless directly related to the ongoing study [14].

Frequency and plans for auditing trial conduct {23}

The trial Steering Committee will discuss trial progress during a meeting every 3 months or more frequently if necessary. In case of any modifications to the protocol, including changes in objectives, design, patient population, sample size, and study procedures, the Ethics Committee, and the journal will be notified as soon as possible. Formal trial auditing will not be carried out because interventions are of low risk.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any modifications to the protocol that may impact the conduct of the study, potential benefit of the patient, or may affect patient safety, including changes in study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be agreed upon by authors, and approved by the Ethics Committee prior to implementation and notified to the health authorities in accordance with local regulations.

Administrative changes to the protocol are minor corrections and/or clarifications that have no effect on the way the study is to be conducted. These administrative changes will be agreed upon authors and will be documented in a memorandum. The Ethics Committee may be notified of administrative changes.

Patient public involvement

Research objectives and study design were influenced to a large extent by discussions with patients regarding their specific concerns and expectations of reconstructive surgery. The results obtained will be included in patient education books, brochures, and handouts and disseminated among females with POP. This study could promote further active involvement of patients and the public in

research design and active participation throughout the research process.

Dissemination plans {31a}

Every attempt will be made to reduce to an absolute minimum the interval between the completion of data collection and the release of the study results. We expect to take about 3 to 4 months to compile the final results paper for an appropriate journal. The study results will be released to the participating doctors, referring specialists, patients, and the general medical community.

No later than 1 year after the collection of the 1-year post-randomization interviews, we will deliver a completely deidentified data set to an appropriate data archive for sharing purposes.

Discussion

The significance of the consistency of level 3 pelvic floor support has already been discussed by researchers. Thus, in a study by Jerry L. Lowder et. al. an increase in the size of the genital gap was assessed as a predictor of the loss of apical support of the pelvic floor. They concluded that an increase in the size of Gh according to the POP-Q system < 3.75 cm is an unfavorable prognostic factor in the development of apical prolapse [15]. The creator of the concept of 3 levels of support for the pelvic organs, John DeLancey, in his study, noted that an increase in the size of the hiatus is directly related to damage of the perineal body, and, consequently, dysfunction of the structures that are attached to it—the muscles of the levator group and the urogenital diaphragm [16]. Chang et. al studied the effect of simultaneous correction of an asymptomatic rectocele by posterior colpoperineoplasty and sacrocolpopexy. The authors noted that one-stage colpoperineoplasty reduces the risk of POP recurrence [9]. However, there are studies that indicate that correction of the posterior compartment and perineum increases the risk of impaired bowel function and de novo dyspareunia [17, 18].

We hope that the results of our study will contribute to increasing the efficiency and safety of reconstructive surgical interventions in POP.

Trial status

The first version of the study is registered in the United States National Library of Medicine [https://clinicaltrials.gov] NCT03958695 from 09.09.2022 г. Recruitment began on the 1st of June of 2023, and it is believed that the recruitment will finish in September of 2023. We expect to finish the trial in September of 2025.

Abbreviation

POP Pelvic organ prolapse

Acknowledgements

Not applicable.

Authors' contributions {31b}

Rustam A. Shakhaliev—drafting and editing the manuscript, literature review, data analysis and interpretation; study design. Andrey S. Shulgin—study concept, critical review, scientific supervision, drafting and editing the manuscript. Nikita D. Kubin—critical review, scientific editing. Anton S. Kondratiev—study concept, study design development, data acquisition. Denis A. Suchkov—drafting and editing the manuscript. Sofia V. Neklasova—editing the manuscript, translation. Dmitry D. Shkarupa—study concept, scientific supervision, final approval.

Funding {4}

The study was not sponsored.

Availability of data and materials {29}

The Principal Investigator will have access to patients' personal data to perform follow-up and review medical records if corrections are required. Any data required to support the protocol can be supplied on request.

Declarations

Ethics approval and consent to participate {24}

This clinical trial will be conducted in accordance with the principles established by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments established by the World Medical Assemblies and the ICH Clinical Practice Guidelines. The study will be conducted in accordance with all international standards and Russian legislation. The protocol of the clinical study, as well as informed consent, were submitted to the ethics committee of the Saint-Petersburg University Hospital on 18.02.2022 г. During the meeting, written approval was received and signed by the chairman and representatives of the ethics committee №02/22 from 24.08.2022. The first version of the study is registered in the United States National Library of Medicine [https://clinicaltrials.gov] NCT03958695 from 09.09.2022 г.

All patients participating in this trial will sign an informed consent for the collection and usage of the data obtained by their doctor.

Patients that are enrolled in the study are covered by indemnity for negligent harm through the standard arrangements. Saint-Petersburg State University Hospital has insurance to cover for non-negligent harm associated with the protocol. This will include cover for additional health care, compensation, or damages awarded by claims pursued through the courts. Incidences judged to arise from negligence (including those due to major protocol violations) will not be covered by study insurance policies.

Consent for publication {32}

Not applicable, as no identifying images or personal/clinical details of participants are shown here, nor will they be included in the trial results reports.

Competing interests {28}

The authors declare that we have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Topics suggested for presentation or publication will be circulated to the *Principal investigators* of the author group. The writing committee will be formed the person making the suggestion about trial design and main principles may be considered as the lead author. Disputes regarding authorship will be settled by the Study Chair after consultation with the Chair of the authors.

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