

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparative study of uterosacral and sacrospinous ligament stabilization surgeries for the treatment of pelvic floor disorders

Protocol summary

Study aim

Comparing the effectiveness and complications of uterosacral and sacrospinous ligament stabilizations for the treatment of pelvic floor disorders

Design

Randomized, Single-blinding clinical trial, with the parallel groups, Phase 2 on 64 patients

Settings and conduct

In this study, 64 patients with pelvic floor disorders presented at Alzahra and Beheshti hospitals in Isfahan are included. They are then randomly divided into two groups. The first group undergoes uterosacral ligament stabilization surgery and the second group undergoes sacrospinous ligament stabilization surgery.

Participants/Inclusion and exclusion criteria

In this study, patients are aged between 18 to 75 years with cervical prolapse grade two or more based on the examination, symptomatic prolapse due to protrusion or intestinal or urinary symptoms, not responding to conservative treatments, requesting surgical treatment for prolapse and consent to participate in the study. Exclusion criteria are a contraindication to major surgery or anesthesia, any malignancy in the urinary, genital and pelvic systems, active urinary tract, genital and pelvic infections, and pregnancy and breastfeeding.

Intervention groups

First intervention group: Patients in this group undergo uterosacral ligament stabilization surgery. Second Intervention group: Patients in this group undergo sacrospinous ligament stabilization surgery.

Main outcome variables

Pelvic Floor Distress Inventory; Sexual function; Recurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N21**

Registration date: **2021-01-18, 1399/10/29**

Registration timing: **prospective**

Last update: **2021-01-18, 1399/10/29**

Update count: **0**

Registration date

2021-01-18, 1399/10/29

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of uterosacral and sacrospinous ligament stabilization surgeries for the treatment of pelvic floor disorders

Public title

Comparing the effects of two types of surgeries including uterosacral and sacrospinous ligament stabilization for the treatment of pelvic floor disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The age between 18 and 75 years old
Cervical prolapse grade two or more based on examination
Symptomatic prolapse for protrusion or intestinal or urinary symptoms
Lack of response to conservative treatments
Demand for surgical treatment for prolapse
Being consent to participate in the study

Exclusion criteria:

Contraindication to major surgery or anesthesia
Existence of any malignancy in the urinary, genital and pelvic systems
Active infection of the urinary, genital and pelvic systems
Pregnancy and breastfeeding

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 64 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the two study groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the present study, the surgeon is aware of the type of surgery in each of the two groups, but the patient and the evaluator (data collector) are not aware of the type of surgery in each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave, Azadi Square.

City

Isfaha

Province

Isfahan

Postal code

8174673461

Approval date

2020-11-26, 1399/09/06

Ethics committee reference number

IR.MUI.MED.REC.1399.757

Health conditions studied

1

Description of health condition studied

Pelvic organ prolapse

ICD-10 code

N81.3

ICD-10 code description

Complete uterovaginal prolapse

Primary outcomes

1

Description

Pelvic floor muscle function

Timepoint

Before and 12 months after the intervention

Method of measurement

Pelvic Floor Distress Inventory Questionnaire-20 (PFDI-20)

2

Description

Sexual function

Timepoint

Before and 12 months after the intervention

Method of measurement

Female Sexual Function Index (FSFI) questionnaire

Secondary outcomes

1

Description

Recurrence of the disease

Timepoint

12 months after surgery

Method of measurement

Clinical examination and Pelvic Floor Distress Inventory questionnaire (PFDI-20)

Intervention groups

1

Description

First intervention group: Patients in this group as the first group undergo uterosacral surgery.

Category

Treatment - Surgery

2

Description

Second intervention group: Patients in this group as the first group undergo sacrospinous surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Maryam Hajhashemi

Street address

Motahari Street.

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8174673461

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hajhashemy73@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Hajhashemi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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City

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available