

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Laparoscopic sacrocolpopexy versus sacrospinous ligament fixation for treatment of prolapse of the apical segment of the vagina

Protocol summary

Study aim

Comparison of efficacy and complications of two laparoscopic sacrocolpopexy and secretion of ligament sacrospinous in vaginal prolapse

Design

Clinical trials with parallel groups were randomly assigned to each group

Settings and conduct

All patients were operated in two groups in the Urology Operative Hospital of Bamonar Hospital in Kerman. The first group was placed in the supine position with a laparoscopic device through the abdomen and the second group in the lithotomy position through the vagina

Participants/Inclusion and exclusion criteria

Entry criteria included 1 - Age 18-75 years 2. grade two or more cervical prolapse in the examination 3-Symptom of prolapse 4. No response to conservative treatment 5. Demand for surgical treatment for the treatment of prolapse And exclusion criteria included 1. There is a contraindication for major surgery or anesthesia 2. There is any malignancy in the urinary system, the vulvovaginal genital area 3. Proactive urinary tract infection, genital and pelvic infection 4. Pregnancy and breastfeeding 5- History of sensitivity to the synthetic mesh

Intervention groups

Group 1: Surgical Laparoscopic sacrocolpopexy Surgery through the abdomen that the vaginal vault is fixed through the mesh with non-absorbance sutures to the sacrum bone. Group 2: Ligament sacrospinous fixation through vagina.vaginal vault fixed through mesh to ligament sacrospinous .

Main outcome variables

symptoms and quality of life complications of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180106038231N1**

Registration date: **2019-11-09, 1398/08/18**

Registration timing: **retrospective**

Last update: **2019-11-09, 1398/08/18**

Update count: **0**

Registration date

2019-11-09, 1398/08/18

Registrant information

Name

Ehsan Zemanati yar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3244 8636

Email address

a.danesh@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Laparoscopic sacrocolpopexy versus sacrospinous ligament fixation for treatment of prolapse of the apical segment of the vagina

Public title
surgery for prolapse

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 18-75 years Cervical prolapse Symptomatic prolapse no response to conservative treatment Demand for surgical treatment for the treatment of prolapse
Exclusion criteria:
 contraindication for surgery malignancy Active genitourinary tract infection pregnancy and breastfeeding hypersensitivity to mesh

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Randomized

Randomization description
blocked randomized : The block randomization method will be used in which both groups are completed in parallel, patient 1 in group 1 and patient 2 in group 2, patient 3 again in group 1 and patient 4 in group 2. Given so both groups will be complete

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Shahid Bahonar Hospital in Kerman, Shahid Gharani St.

City

Kerman

Province

Kerman

Postal code

7619714368

Approval date

2018-06-08, 1397/03/18

Ethics committee reference number

IR.KMU.REC.1397.094

Health conditions studied

1

Description of health condition studied

Apical vaginal prolapse

ICD-10 code

N99.3

ICD-10 code description

Prolapse of vaginal vault after hysterectomy

Primary outcomes

1

Description

sign and symptom

Timepoint

Follow up 12 months after surgery

Method of measurement

Using a questionnaire and examination

2

Description

quality of life

Timepoint

Follow up 12 months after surgery

Method of measurement

Using a questionnaire and examination

3

Description

sexual function

Timepoint

Follow up 12 months after surgery

Method of measurement

Using a questionnaire and examination

4

Description

complication

Timepoint

Follow up 12 months after surgery

Method of measurement

Using a questionnaire and examination

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: A group of patients undergoing laparoscopic sacrocolpopexy

Category

Treatment - Surgery

2

Description

Intervention group: the second group of patients undergoing surgical stabilization of sacrospinous ligament through the vagina

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital in Kerman

Full name of responsible person

Zemanati Yar Ehsan

Street address

Shahid Gharani Street

City

Kerman

Province

Kerman

Postal code

7619714368

Phone

+98 34 3223 5011

Email

drehsan.zemanati@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr.Abas Pardakhti

Street address

Kerman University of Medical Sciences, Haft Bagh

City

Kerman

Province

Kerman

Postal code

14678213675

Phone

+98 34 3133 6086

Email

a.pardakhti@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Zemanati Yar Ehsan

Position

Rezident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Shahid Bahonar Hospital in Kerman

City

Kerman

Province

Kerman

Postal code

7619714368

Phone

+98 34 3223 5011

Email

drehsan.zemanati@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Zemanati Yar Ehsan

Position

Rezident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Shahid Bahonar Hospital in Kerman, Shahid Gharani St.

City

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Province

Kerman

Postal code

7619714368

Phone

+98 34 3223 5011

Email

drehsan.zemanati@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Ehsan Zemanati yar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Gharani st bahonar hospital

City

Kerman

Province

Kerman

Postal code

7619714368

Phone

+98 34 3244 8636

Fax

Email

drehsan.zemanati@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total quality of life data and symptoms and complications after being unidentifiable can be shared

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers at universities

Under which criteria data/document could be used

Conditions under academic rules

From where data/document is obtainable

drehsan.zemanati@yahoo.com

What processes are involved for a request to access data/document

The university approval process involves the approval of the group and the research committee of the university

Comments