

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study the results of pelvic floor prolapsed repair in vaginal surgery (anterior colporrhaphy with mesh and Sacrospinous ligament suspension) and abdominal approach (Sacropexy and Hysteropexy)

Protocol summary

Comparison of the incidence of dyspareunia in two methods

Study aim

Compare the results of pelvic floor prolapsed repair in vaginal surgery (anterior colporrhaphy with mesh and Sacrospinous ligament suspension) and abdominal approach (Sacropexy and Hysteropexy)

Design

The study population is divided into two parts of the intervention group. Group one (: Patients undergoing pelvic floor prolapse surgery in vaginal (anterior corpuscular with mesh and Sacrospinosis) and group two Patients undergoing pelvic floor prolapse surgery in vaginal (anterior corpuscular with mesh and Sacrospinosis) with 25 populations in each group. They will be selected among the patients (female) referred to the clinic Al-Zahra Hospital in Tabriz by Random sampling method.

Settings and conduct

The study population is divided into two parts of the intervention group. Group one (: Patients undergoing pelvic floor prolapse surgery in vaginal (anterior corpuscular with mesh and Sacrospinosis) and group two Patients undergoing pelvic floor prolapse surgery in vaginal (anterior corpuscular with mesh and Sacrospinosis) with 25 populations in each group. They will be selected among the patients (female) referred to the clinic Al-Zahra Hospital in Tabriz by Random sampling method.

Participants/Inclusion and exclusion criteria

In this study, women referred to Al-Zahra clinic who have pelvic floor disease in Grade I and II will be examined in the absence of previous surgery history

Intervention groups

1- Intervention group one: Patients undergoing pelvic floor prolapse surgery in vaginal (anterior corpuscular with mesh and Sacrospinosis) 2- Patients undergoing abdominal surgery (Sacropaxia and Hysteropexy).

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130306012728N6**

Registration date: **2018-07-29, 1397/05/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-29, 1397/05/07**

Update count: **0**

Registration date

2018-07-29, 1397/05/07

Registrant information

Name

Sakineh Hajebrahimi

Name of organization / entity

Urology Department, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7328

Email address

ebrahimis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-01, 1397/04/10

Expected recruitment end date

2019-04-30, 1398/02/10

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study the results of pelvic floor prolapsed repair in vaginal surgery (anterior colporrhaphy with mesh and Sacrospinous ligament suspension) and abdominal approach (Sacropexy and Hysteropexy)

Public title
Study the results of pelvic floor prolapsed repair in vaginal surgery (anterior colporrhaphy with mesh and Sacrospinous ligament suspension) and abdominal approach (Sacropexy and Hysteropexy)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Pelvic floor prolapse three or four grade Dissatisfaction or non-response to non-surgical treatments Satisfaction to participate in the study
Exclusion criteria:
There is an anatomical problem that does not allow surgery to be performed in a way There is a risk factor or specific disease that does not allow surgery to be performed in either of the two methods History of previous pelvic floor prolapse surgery dissatisfaction to participate in the study

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients with using a random number table based on the case number, will be randomly assigned into two intervention and control groups

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences.

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

33357313

Approval date

2018-04-23, 1397/02/03

Ethics committee reference number

IR.TBZMED.REC.1397.094

Health conditions studied

1

Description of health condition studied

Pelvic floor prolapse

ICD-10 code

N81.8

ICD-10 code description

Other female genital prolapse

Primary outcomes

1

Description

Evaluation of duration of hospitalization in pelvic floor prolapse surgery in two methods

Timepoint

Duration of hospitalization

Method of measurement

Questionnaire

2

Description

Evaluation of surgical duration of pelvic floor prolapse in two methods

Timepoint

Duration of surgery

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Comparison of the incidence of dyspareunia in two

methods

Timepoint

Follow up every month until three months after surgery

Method of measurement

Calling and completing the questionnaire

Intervention groups

1

Description

Intervention group:

Category

Treatment - Surgery

2

Description

Intervention group:

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Prof. Sakineh Hajebrahimi

Street address

Alzahra Hospital, South Artesh St.

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

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+98 41 3553 9161

Email

lahroudin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Alireza Rashidi

Street address

Third Floor, Central Building of Number2, Golgasht Street

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5138665793

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Email

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for Research,Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Prof. Sakineh Hajebrahimi

Position

Professor of Urology, Fellowship in Female Urology

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Department of Urology,Imam Reza educational and treatment center, Golgasht Street, Tabriz, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available