

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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

**Phone**

+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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138665793

**Phone**

+98 41 3553 9161

**Email**

lahroudin@gmail.com

**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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

04151666-14756

**Phone**

+98 984133357328

**Email**

lahroudin@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

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+98 984133357328

**Email**

lahroudin@gmail.com

**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