

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of modified partial colpocleisis in elderly women with severe pelvic organ prolapse and sexual activity

#### Protocol summary

##### Summary

Pelvic organ prolapsed is main cause of disability of women with multi vaginal delivery. The common surgical approach for therapy is vaginal hysterectomy. In elderly women with medical problem who do not wish to be sexually active, partial colpocleisis (lefort) is a simple, safe, and effective surgical procedure that reliably relieves these women of their symptoms without the potential hazards of vaginal hysterectomy. In this clinical trial study we use modified lefort procedure for repair of pelvic organ prolapsed with leave one lateral vaginal channel larger than other, so it suitable for sexual activity. In this study, patients were divided into two groups, surgical vaginal hysterectomy (control) and surgical modified partial colpocleisis (case). Patient with uterine prolapsed older than 65 years old without other pathologic problem who wish to be sexually active were chosen. Duration, complication, efficacy and patient satisfactory of modified partial colpocleisis for severe pelvic organ prolapsed comparison with vaginal hysterectomy at Alzahra hospital of Tabriz university of medical sciences.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013060811205N2**

Registration date: **2013-10-24, 1392/08/02**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-10-24, 1392/08/02

##### Registrant information

**Name**

Dr.Zahra Fardiazar

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1553 9161

##### Email address

fardiazar@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-08-11, 1392/05/20

##### Expected recruitment end date

2015-07-11, 1394/04/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of modified partial colpocleisis in elderly women with severe pelvic organ prolapse and sexual activity

##### Public title

Evaluation of modified partial colpocleisis in elderly women with severe pelvic organ prolapse and sexual activity

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age above 65 years old; no indication for hysterectomy total uterine prolapse exclusion criteria: medical conditions lead to lower abdomen pressure such

as Constipation Chronic persistent cough; Patients Who Want to Stop Their treatment

#### Age

From **65 years** old to **90 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **20**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### 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

Tabriz University of Medical Sciences, Golgasht avenue

###### City

Tabriz

###### Postal code

##### Approval date

2012-05-15, 1391/02/26

##### Ethics committee reference number

2371/4/5

### Health conditions studied

#### 1

##### Description of health condition studied

Female genital prolapse

##### ICD-10 code

N81.8

##### ICD-10 code description

Old laceration of muscles of pelvic floor

### Primary outcomes

#### 1

##### Description

Comparative effects of short-term and medium-term (first year) in two methods.

##### Timepoint

During the first year after surgery.

##### Method of measurement

Questionnaire

#### 2

##### Description

Duration of vaginal hysterectomy and colpoctisis

##### Timepoint

During surgery

##### Method of measurement

check list

#### 3

##### Description

Assess patients' satisfaction with sexual function

##### Timepoint

During the first year after surgery.

##### Method of measurement

Questionnaire

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

modified partial colpoctisis

##### Category

Treatment - Surgery

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Alzahra hospital

###### Full name of responsible person

Dr.Zahra Fardiazar

###### Street address

Alzahra hospital, South Artesh ave

###### City

Tabriz

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Vice chancellor for research, Tabriz University of

Medical Sciences

**Full name of responsible person**

Dr.Ali Reza Ostad Rahimi

**Street address**

Tabriz university of medical sciences, Golgasht street

**City**

Tabriz

**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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tabriz University Of Medical Sciences

**Full name of responsible person**

Dr.Zahra Fardiazar

**Position**

Proffessor

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**Web page address**

**Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*