

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

Other areas of specialty/work

Street address

Alzahra hospital,South Artesh avenue

City

Tabriz

Postal code

Phone

+98 41 1553 9161

Fax

Email

fardiazar@tbzmed.ac.ir; lahrodi59@yahoo.com; wrhrcenter@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Dr.Zahra Fardiazar

Position

proffessor

Other areas of specialty/work

Street address

Alzahra hospital, South Artesh avenue

City

Tabriz

Postal code

Phone

+98 41 1553 9161

Fax

Email

fardiazar@tbzmed.ac.ir; ro_zavarnia@hotmail.com; wrhrcenter@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Dr.Zahra Fardiazar

Position

proffessor

Other areas of specialty/work

Street address

Alzahra hospital,South Artesh avenue

City

Tabriz

Postal code

5138665793

Phone

+98 41 1553 9161

Fax

Email

fardiazar@tbzmed.ac.ir; ro_zavarnia@hotmail.com; wrhrcenter@gmail.com

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