Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of modified partial colpoclisis in elderly women with sever 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 (lefotrh) 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 lefotrh 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 colpoclisis(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 partiel colpoclesis 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

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Iran (Islamic Republic of)

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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 colpoclisis in elderly women with sever pelvic organ prolapse and sexual activity

Public title

Evaluation of modified partial colpoclisis in elderly women with sever pelvic organ prolapse and sexual activity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:age above 65 years old; no indication for hysterectomy total uterine prolaps 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 Ssciences, 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 colpoclisis

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 colpoclisis

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

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Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,Tabriz University of

Medical Scienes

Full name of responsible person
Dr.Ali Reza Ostad Rahimi

Street address
Tabriz university of medical sciences, Golgasht street

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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 Scienes

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
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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