

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of quality of life in women with pelvic organ prolapse before and after using pessary

Protocol summary

Summary

The aim of this study is comparison of quality of life in women with pelvic organ prolapse before and after using pessary. Sixty patients who referred to Al-Zahra and Taleghani hospital with pelvic organ prolapse will be selected for study. All patients will be suggested to treat by surgery or using pessary and those who selected pessary will be included in our study. Patients with malignant problems, asthma and heart disease and risk for surgery will be excluded from study. On examination, the amount of prolapse will be determined by, Pelvic Organ Prolapse Quantification System (POP-Q). In the absence of contraindications, suitable treatment of topical estrogen containing conjugated estrogen twice a week before inserting pessary and once a week after inserting pessary will be prescribed for all menopausal women. Before inserting pessary, the problems like vaginal ulcers, abnormal bleeding or infection must be treated. After three times inserting pessary, improper placement, causing pain or patient deterred from using it will be considered unsuccessful inserting pessary. All patients will be taught how to clean and keep pessary. Follow-up visits will be done after one week, three months and six months. During the follow-up visits, about the side effects of pessary like discomfort, get out of pessary, incontinence and difficulty in urination or bowel movements and vaginal bleeding will be asked from patients. At every visit, pessary moved out and cleaned and before re-inserting, the vaginal examination for the presence of erosion and the infection will be checked. In the absence of any problem, pessary will be inserted again and next visit will be scheduled. Compliance therapy for using pessary was considered more than two months. Two questionnaires contain urinary symptoms urogenital distress inventory (UDI-6 and quality of life incontinence impact questionnaire-7 (IIQ-7) before treatment, three months and six months after treatment for evaluating the effectiveness of treatment will be used. If treatment is discontinued,

cause of discontinuation will be recorded. This study is a before and after.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072618311N2**

Registration date: **2016-08-31, 1395/06/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-31, 1395/06/10

Registrant information

Name

Parvin Bastani

Name of organization / entity

Tabriz University of medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1443 5590

Email address

bastanip@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research, Tabriz University Of Medical Sciences

Expected recruitment start date

2016-08-20, 1395/05/30

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of quality of life in women with pelvic organ prolapse before and after using pessary

Public title

The effect of pessary usage in the treatment of prolapse of pelvic organs.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Women with pelvic organ prolapse symptoms; Women between 40 to 80 years Exclusion criteria: Patients with malignant problems of women; asthma; heart disease and risk for surgery

Age

From **40 years** old to **80 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

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

Postal code**Approval date**

2016-06-25, 1395/04/05

Ethics committee reference number

IR.TBZMED.REC.1395.269

Health conditions studied**1****Description of health condition studied**

Prolapse Of Pelvic Organs

ICD-10 code

N81

ICD-10 code description

Prolapse Of Pelvic Organs

Primary outcomes**1****Description**

Urinary Symptoms

Timepoint

Before intervention; three months after intervention; three months after intervention

Method of measurement

Pelvic Organ Prolapse Quantification System (POP-Q)

Secondary outcomes**1****Description**

Quality of life

Timepoint

Before treatment, three months and six months after treatment

Method of measurement

questionnaire (Incontinence quality of life =I-QOL)

Intervention groups**1****Description**

Intervention group: Put a pessary into the vagina, Made in America, mylex brand, Approved by America FDA

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Dr.Parvin Bastani Alamdari

Street address

Alzahra Hospital, South Artesh St.,Tabriz, iran

City

Tabriz

2

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Dr.Parvin Bastani Alamdari

Street address

Taleghani Hospital, Rah Ahan St.,Tabriz, iran

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.Alireza Rashidi

Street address

Third Floor, Central Building of Number2, 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

Parvin Bastani Alamdari

Position

Associate Professor of Obstetrics and Gynecology

Other areas of specialty/work

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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