

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**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*