Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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

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 afte rintervention; three months afte rintervention
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
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Tabriz

2

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Dr.Parvin Bastani Alamdari
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Taleghani Hospital, Rah Ahan St.,Tabriz, iran
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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
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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 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

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Name of organization / entity
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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