

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of vaginal pessary implantation on quality of life, sexual self-efficacy and clinical management of care in women with uterine prolapse

Protocol summary

Study aim

Determining the effect of vaginal pessary placement on quality of life, sexual self-efficacy and in women with uterine prolapse

Design

The present study is a quasi-experimental study of pre-test-post-test type. 72 individuals will be selected to participate in the study using available sampling and will be randomly assigned to the intervention and control groups. The number of sample volumes in each group is 30 people and 36 people in each group, taking into account the 10% drop. There is no blinding. After collecting data, questionnaires will be extracted and in SPSS software.

Settings and conduct

Research community of women aged 45-60 years with uterine prolapse in Tehran. Research environment of Arash Hospital and Taleghani Hospital and private offices of physicians. The questionnaire is given once before the intervention and once 8 weeks later. no action is taken for the control group.

Participants/Inclusion and exclusion criteria

-Inclusion criteria : Women aged 45-60 years, Married women living together with their husbands, Literacy, Willingness and interest in participating in the study, Minimum grade 1 prolapse, Tendency to use pessary instead of surgery, Having pessary placement conditions, Lack of vaginitis -Exclusion criteria: People who refuse to cooperate in filling out the questionnaire and continuing the study, Increased vaginal discharge and infection and the patient's unwillingness to continue using the pessary.

Intervention groups

The intervention group is those who have prolapse or do not want surgery or have contraindications for surgery due to the underlying disease and their choice is a pessary. The control group is those who have uterine prolapse and do not want to have a pessary implant.

Main outcome variables

Improving quality of life and sexual efficiency; pessary

clinical care management; Promoting sexual satisfaction in women with prolapse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110425006284N17**

Registration date: **2022-07-27, 1401/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-27, 1401/05/05**

Update count: **0**

Registration date

2022-07-27, 1401/05/05

Registrant information

Name

Maryam Modarres

Name of organization / entity

Tehran university of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of vaginal pessary implantation on quality of life, sexual self-efficacy and clinical management of care in women with uterine prolapse

Public title
The effect of pessary on the clinical care of women with prolapse

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 45-60 years Married women and women living together with their husbands Literacy Willingness and interest in participating in the study Minimal first-degree prolapse Tendency to use pessary instead of surgery Lack of vaginitis
Exclusion criteria:
Having vaginal discharge and infection and the patient's unwillingness For pessary placement..

Age
From **45 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

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 Tehtan University of Medical Sciences

Street address

Tohid Square, Dr. Mirkhani St. (Eastern Nusrat),

City

Tehran

Province
Tehran

Postal code
1419733171

Approval date
2022-04-10, 1401/01/21

Ethics committee reference number
IR.TUMS.FNM.REC.1401.002

Health conditions studied

1

Description of health condition studied

Uterine prolapse

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Correction of uterine prolapse

Timepoint

At the beginning of the study (before the intervention) and once 8 weeks after the intervention

Method of measurement

Pelvic Organ Prolapse Quantification (POP-Q) System

Secondary outcomes

1

Description

Quality of life and sexual self-efficacy and management of patient clinical care

Timepoint

Once at the beginning of the study (before the intervention) and once 8 weeks after the intervention

Method of measurement

Quality of Life Questionnaire in Women with Prolapse (P-QOL), Vaziri and Lotfi Self-Efficacy Questionnaire, PGI Three-Question Scale Questionnaire, Researcher-Managed Clinical Care Questionnaire

Intervention groups

1

Description

Intervention group: The intervention group are those who have uterine prolapse and tend to have a pessary implantation and meet the inclusion criteria. For this group, a silicone device called a pessary is used to treat uterine prolapse. This device is available in different sizes and models and is a non-invasive method for patients whose choice is not surgery. In this study, two types of Marland and ring with support are used. And the choice of pessary depends on the patient's examination. For grade 1 and 2 prolapse, a ring with support is used,

and for grade 3 and 4 prolapse, a Marland . Sex is possible in two types of pessarys at the same time. The pessary is placed after the necessary training and filling out the questionnaire based on the patient's examination and 8 weeks later she returns again for control and re-examination.

Category

Treatment - Devices

2

Description

Control group: There are people who have uterine prolapse but for personal reasons do not want to have a pessary. These patients are given the necessary training on pessary and placement and no treatment is performed for them. vaginal examination is performed and the type of prolapse is recorded. The questionnaire is filled out by these patients at the first visit and patient follow-up is maintained by telephone at 4 weeks after placement and 8 weeks after placement.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr. Soodabeh Darvish

Street address

Shahid Chamran Highway, Yemen St. Shahid Arabi St., Ayatollah Taleghani Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Tohid Square, Dr. Mirkhani St. (Eastern Nusrat)

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Maryam Modarres

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available