

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of Sexual Function Before and After Using a Pessary in Women with Pelvic Floor Disorders

Protocol summary

Study aim

Comparison of sexual function before and after using a pessary in women with pelvic floor disorders.

Design

This study will be performed on all women referred to the Al-Zahra Educational Center with the diagnosis of pelvic floor disorder. This study will be Befor-After. It will be conducted as a clinical trial within 2 years. Sampling will be done with easily method. (According to estimates from previous years, the maximum will be 30). This study is not blind.

Settings and conduct

Sixty patients who referred to Al-Zahra and Taleghani hospital with pelvic organ prolapse will be selected for study.

Participants/Inclusion and exclusion criteria

Patients over the age of 18 and married will be included in the study and will not be included in the study if there is a problem with early ejaculation of the spouse and the age under 18 years

Intervention groups

All patients who referred to Alzahra's Alzahra Medical Education Center for two years of study with pelvic floor disorders and have an indication of the use of a pessary

Main outcome variables

Sexual function; Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101222005448N4**

Registration date: **2019-01-21, 1397/11/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-21, 1397/11/01**

Update count: **0**

Registration date

2019-01-21, 1397/11/01

Registrant information

Name

Fateme Mallah

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41133336360

Email address

mallahf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-06, 1397/06/15

Expected recruitment end date

2019-12-06, 1398/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sexual Function Before and After Using a Pessary in Women with Pelvic Floor Disorders

Public title

Comparison of Sexual Function Before and After Using a Pessary in Women with Pelvic Floor Disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction to participate in the study The ability to have

sex Married Age 18 and above Pelvic floor disorders that do not have surgical indication

Exclusion criteria:

Having a history of chronic diseases (diabetes - high blood pressure - heart disease) affecting sexual function (in each of the couples) Sexual problems in the spouse such as premature ejaculation and impotence Drinking alcohol (in each of the couples)

Age

From **18 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Province

East Azarbaijan

Postal code

5166616471

Approval date

2019-01-07, 1397/10/17

Ethics committee reference number

IR.TBZMED.REC.1397.835

Health conditions studied

1

Description of health condition studied

Prolapse Of Pelvic Organs

ICD-10 code

N81

ICD-10 code description

Female genital prolapse

Primary outcomes

1

Description

Sexual function

Timepoint

Before intervention; ۳ weeks after the intervention; three months after intervention

Method of measurement

International Prolaps-Urinary Incontinenc Sexual Function(PISQ-12)

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention; ۳ weeks after the intervention; three months after intervention

Method of measurement

International Prolapse-Urinary Incontinence Sexual Function(PISQ-12)

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

Fateme Mallah

Street address

Alzahra Hospital, South Artesh St.

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5138665793

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Email
lahroudin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for Research,Tabriz University Of
Medical Sciences

Full name of responsible person
Abolghasem Juiban

Street address
Third Floor, Central Building of Number2, Golgasht
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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

Vice chancellor for Research,Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Fateme Mallah

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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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