Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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

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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; فwo weeks after the intervention; three months afte rintervention

Method of measurement

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

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention; فwo weeks after the intervention; three months afte rintervention

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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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
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Third Floor, Central Building of Number2, Golgasht Street
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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
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Fateme Mallah
Position
Associate Professor
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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