

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of perineuropathy and posterior anterior repair (APR) on body image, sexual function and quality of life in postoperative women

#### Protocol summary

##### Study aim

The effect of perineuropathy and posterior anterior repair (APR) on body image, sexual function and quality of life in postoperative women

##### Design

A clinical trial without a control and non-blind group in which the study and randomization phase does not apply in this study on 119 female patients with rectocele, cystocele and uterine prolapse who are candidates for perineural surgery and posterior anterior repair (APR)

##### Settings and conduct

The researcher refers to the mentioned hospitals. While introducing himself to the clients he talks about the study and its goals and explains the ethical considerations. The informed consent form is obtained from the subjects. Then three questionnaires of women's sexual satisfaction body image and quality of life; It is explained to the patients and in case of complete and informed consent it is delivered to them and collected after completion. Patients undergo perineurography and anterior-posterior repair (APR). Six months after the above operation, three questionnaires are completed again.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: women with rectocele, cystocele and uterine prolapse candidate for perineuropathy and posterior anterior repair (APR) surgery; consent to enter the study. Exclusion criteria: lack of access to the subject for follow-up; do not tend to continue participation in the study

##### Intervention groups

Women with rectocele, cystocele and uterine prolapse, etc., who are candidates for perineuropathy and posterior anterior repair (APR) surgery; Are selected. They undergo perineurectomy and posterior anterior repair (APR).

##### Main outcome variables

Body image, sexual function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160521027998N9**

Registration date: **2021-04-15, 1400/01/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-15, 1400/01/26**

Update count: **0**

##### Registration date

2021-04-15, 1400/01/26

##### Registrant information

##### Name

Maryam Hajihashemi

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3776 6578

##### Email address

m\_hajihashemy@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-19, 1399/12/01

##### Expected recruitment end date

2022-02-20, 1400/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effect of perineuropathy and posterior anterior repair (APR) on body image, sexual function and quality of life in postoperative women

**Public title**

The effect of perineuropathy and posterior anterior repair (APR) in postoperative patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women with rectocele, cystocele and uterine prolapse candidate for perineural surgery and posterior anterior repair (APR) Satisfaction to enter the research

**Exclusion criteria:**

Exclusion of the subject from the study Lack of access to the subject to follow up

**Age**

From **25 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **119**

**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 Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Azadi Square

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8184853541

**Approval date**

2020-10-07, 1399/07/16

**Ethics committee reference number**

IR.MUI.MED.REC.1399.583

**Health conditions studied****1****Description of health condition studied**

Rectocell

**ICD-10 code**

N81.6

**ICD-10 code description**

Rectocele

**2****Description of health condition studied**

Cystocell

**ICD-10 code**

N81.1

**ICD-10 code description**

Cystocele

**3****Description of health condition studied**

uterine prolapse

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Body image

**Timepoint**

Before surgery and six months after surgery

**Method of measurement**

Questionnaire MBSRQ

**2****Description**

Sexual function

**Timepoint**

Before surgery and six months after surgery

**Method of measurement**

Questionnaire FSFI

**Secondary outcomes****1****Description**

Quality of Life

**Timepoint**

Before surgery and six months after surgery

**Method of measurement**

questionnaire sf-36

## Intervention groups

### 1

#### Description

Intervention group: This study is performed among patients referred to Isfahan women's centers and hospitals. Women who have been diagnosed with rectocele, cystocele and uterine prolapse, etc., and are candidates for perineuropathy and posterior anterior repair (APR) surgery; Are selected. Due to the immorality of depriving patients of treatment, it is not possible to select a control group. Sampling is done by available census. The researcher refers to the mentioned hospitals. While introducing himself to the clients, he talks about the study and its goals and explains the ethical considerations. The informed consent form is obtained from the subjects. Then three questionnaires of women's sexual satisfaction, body image and quality of life; It is explained to the patients and in case of complete and informed consent, it is delivered to them and collected after completion. Patients undergo perineurography and posterior anterior repair (APR). Six months after the above operation, three questionnaires of women's sexual satisfaction, body image and quality of life, distribution, completion and collection are again.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Beheshti hospital

##### Full name of responsible person

Maryam Hajhashemi

##### Street address

Beheshti hospital, Motahhari street

##### City

Esfahan

##### Province

Isfahan

##### Postal code

8184853542

##### Phone

+98 31 3236 3500

##### Email

hajhashemy73@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

Alzahra hospital

##### Full name of responsible person

Maryam Hajhashemi

##### Street address

Al-Zahra Hospital, Shahid Keshvari Highway, Sofeh Boulevard

##### City

Esfahan

##### Province

Isfahan

##### Postal code

8174675731

##### Phone

+98 21 3620 2020

##### Email

hajhashemy73@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Shaghayegh Haghjoi Javanmard

##### Street address

Vice Chancellor for Research and Technology, Isfahan University of Medical Sciences, Hezar Jerib St.

##### City

Esfahan

##### Province

Isfahan

##### Postal code

7346181746

##### Phone

+98 31 3668 8138

##### Email

hajhashemy73@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Maryam Haj Hashemi

##### Position

Assistant professor

##### Latest degree

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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Assistant professor

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data can be shared

**When the data will become available and for how long**

After publishing the article

**To whom data/document is available**

Scientific and academic researchers

**Under which criteria data/document could be used**

Use research documents to benefit from experiences

**From where data/document is obtainable**Executor of the project, Maryam Haj Hashemi,  
hajhashemy73@yahoo.com**What processes are involved for a request to access data/document**

After viewing the request, the documents will be sent.

**Comments**