Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Iran (Islamic Republic of)
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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
Isfehan
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

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2

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Maryam Hajhashemi

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Al-Zahra Hospital, Shahid Keshvari Highway, Sofeh Boulevard

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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.

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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

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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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 researchersl
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