

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of pelvic floor myofascial release and Pelvic floor training on treatment of male erectile dysfunction in post adenectomy and radical prostatectomy

Protocol summary

Study aim

The aim of this project is to evaluate the effect of manual therapy along with exercise therapy on the erection rate of patients after adenectomy and radical prostatectomy.

Design

Clinical randomized trial with control group, with parallel groups, two-way blind, concealed, phase 2 on 80 patients, block method and random number table were used for randomization.

Settings and conduct

The study site will be the special clinic of Imam Reza Hospital in Mashhad, room 24. Patients will be treated for 10 sessions.

Participants/Inclusion and exclusion criteria

Entry conditions: Patients in the age range of 45 to 60 years Confirmation of erectile dysfunction duo to prostate surgery by a physician Patients operated by retropubic technique with both adenectomy and radical methods No entry conditions: Having other neurological diseases and major orthopedic problems (pelvic fractures) Taking erectile drugs such as taladafil and sildenafil Mental problems such as depression

Intervention groups

Case group 1- Manual therapy with therapeutic practice in adenectomy surgery Control group 1- Exercise therapy in adenectomy surgery Case group 2- Manual therapy with therapeutic practice in radical surgery Control group 2- Exercise therapy in radical surgery

Main outcome variables

Erection rate; Erectile condition; Maximum thickness of the ischemic vein; Area of Ischiocavernus; Maximum thickness of bulbouspongiosus ; Area of bulbous sponges; Maximum cavernosal systolic velocity, minimum cavernosal diastolic velocity; Cavernosal artery diameter; Vascular resistance index; Maximum blood velocity in the posterior vein.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210809052123N1**

Registration date: **2022-05-08, 1401/02/18**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-08, 1401/02/18**

Update count: **0**

Registration date

2022-05-08, 1401/02/18

Registrant information

Name

Mahdi Afshar Safavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3225 7030

Email address

mahdi3068@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-06, 1401/02/16

Expected recruitment end date

2022-07-07, 1401/04/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of pelvic floor myofascial release and Pelvic floor training on treatment of male erectile dysfunction in post adenectomy and radical prostatectomy

Public title

The effect of manual therapy on erectile dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of the absence of a secondary erection to prostate surgery by a physician Patients operated by retropubic technique with both adenectomy and radical methods Being married Age range between 45 to 60 years

Exclusion criteria:

Taking erectile drugs such as taladafil and sildenafil Mental problems such as depression

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided into four random groups using a random number constructor. The randomization method is simple and done individually. In order to randomize the statistics, the names of the people are entered in Excel software, then random numbers are assigned to each person using the Rand function. These numbers are then sorted from small to large using software sorting, which disrupts the order of the initial list and randomizes how people are positioned. Then, the first 20 people are considered for the treatment group of adenectomy patients, the second 20 people are considered for the control group of adenectomy surgery, the third 20 people are considered for the treatment group of radical patients and the fourth 20 people are considered for the control group of radical patients. Randomization of patients was done by a statistical consultant and the groups will be determined based on number 1 for the treatment group of adenectomy patients, number 2 for the control group of adenectomy surgery, number 3 for the treatment group of radical patients and number 4 for the control group of radical patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

1- Participants: In the case group, the application of the manual technique is performed in a real way, while in the control group, only a superficial touch is performed and

the therapeutic exercise component is performed in the same way in both. 2- Data Analyzer: The data analyzer will use code to analyze the data in such a way that it is unaware of its content.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

No. 11/1 , Pejman 1, Ebadi 47 , Ayatollah Ebadi St , Mashhad

City

Tehran

Province

Tehran

Postal code

9193798711

Approval date

2022-01-09, 1400/10/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.714

Health conditions studied

1

Description of health condition studied

Erectile dysfunction

ICD-10 code

N52.9

ICD-10 code description

Male erectile dysfunction, unspecified

Primary outcomes

1

Description

Erection hardness

Timepoint

Outcome will be measured at both the beginning and end of treatment

Method of measurement

Erection hardness score

2

Description

Erection index
Timepoint
Outcome will be measured at both the beginning and end of treatment
Method of measurement
International index of erectile function Questionnaire

3

Description
Maximum thickness of Ischiocavernus
Timepoint
Outcome will be measured at both the beginning and end of treatment
Method of measurement
measured by two-dimensional ultrasound

4

Description
Maximum thickness of bulbospongios
Timepoint
Outcome will be measured at both the beginning and end of treatment
Method of measurement
measured by two-dimensional ultrasound

5

Description
Area of Ischiocavernus
Timepoint
Outcome will be measured at both the beginning and end of treatment
Method of measurement
measured by two-dimensional ultrasound

6

Description
Area of bulbospongios
Timepoint
Outcome will be measured at both the beginning and end of treatment
Method of measurement
measured by two-dimensional ultrasound

7

Description
Maximum cavernosal systolic velocity
Timepoint
Outcome will be measured at both the beginning and end of treatment
Method of measurement
measured by color ultrasound

8

Description
Minimum diastolic velocity of cavernosal artery
Timepoint
Outcome will be measured at both the beginning and

end of treatment
Method of measurement
measured by color ultrasound

9

Description
Cavernosal artery diameter
Timepoint
Outcome will be measured at both the beginning and end of treatment
Method of measurement
measured by color ultrasound

10

Description
Maximum blood velocity in the posterior vein
Timepoint
Outcome will be measured at both the beginning and end of treatment
Method of measurement
measured by color ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group 1: Adenectomy surgery patients who will undergo manual therapy and exercise therapy. In these patients, the muscles of the ischiocavernus and bulbospongios are released by massage. The therapist performs this technique with his index finger. The massage is performed for ten minutes. Patients will be treated for ten sessions, three sessions per week. Exercise therapy in these patients is such that the individual is instructed to selectively contract his ischiocavernus muscle and hold this contraction for 7 seconds. Then rest for 7 seconds. The person is also taught how to lift the testicles in front of a mirror. he dose this exercise for ten minutes.

Category
Rehabilitation

2

Description
Intervention group: Intervention group 2: Radical surgery patients who will undergo manual therapy and exercise therapy. In these patients, the muscles of the ischiocavernus and bulbospongios are released by massage. The therapist performs this technique with his index finger. The massage is performed for ten minutes. Patients will be treated for ten sessions, three sessions per week. Exercise therapy in these patients is such that the individual is instructed to selectively contract his ischiocavernus muscle and hold this contraction for 7 seconds. Then rest for 7 seconds. The person is also

taught how to lift the testicles in front of a mirror. he dose this exercise for ten minutes.

Category

Rehabilitation

3

Description

Control group: Control group1 : Adenectomy surgery patients who will undergo exercise therapy. Patients will be treated for ten sessions, three sessions per week. Exercise therapy in these patients is such that the individual is instructed to selectively contract his ischiocavernosus muscle and hold this contraction for 7 seconds. Then rest for 7 seconds. The person is also taught how to lift the testicles in front of a mirror. he dose this exercise for ten minutes.

Category

Rehabilitation

4

Description

Control group: Control group1 : Radical surgery patients who will undergo exercise therapy. Patients will be treated for ten sessions, three sessions per week. Exercise therapy in these patients is such that the individual is instructed to selectively contract his ischiocavernosus muscle and hold this contraction for 7 seconds. Then rest for 7 seconds. The person is also taught how to lift the testicles in front of a mirror. he dose this exercise for ten minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mahdi Afshar Safavi

Street address

Imam Reza Hospital Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9193798711

Phone

+98 910 500 1656

Email

mahdi3068@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farshad Okhovatian

Street address

Faculty of Rehabilitation Sciences, Shahid Beheshti University of Medical Sciences , In front of Bu Ali Hospital, Imam Hossein Square , tehran

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 912 327 7524

Email

farshadokhovatian1965@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahdi Afshar Safavi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

no 11/1 . pejman 1 , ebadi 47 , mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9193798711

Phone

+98 51 3225 7030

Fax

Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahdi Afshar Safavi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

no 11/1 , pejman 1 , ebadi 47 . mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9193798711

Phone

+98 51 3225 7030

Fax

Email

mahdi3068@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahdi Afshar Safavi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

no 11/1 , pejman 1 , ebadi 47 , mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9193798711

Phone

+98 51 3225 7030

Fax

Email

mahdi3068@gmail.com

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 is shared after people are not identified and the article is published.

When the data will become available and for how long

The access period will start 2 months after the results are published

To whom data/document is available

It will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

There is no specific condition

From where data/document is obtainable

Dr. Mehdi Afshar Safavi Phone number +989105001656

No. 11/1 , Pejman 1 , Ebadi 47, Mashhad,

What processes are involved for a request to access data/document

The applicant can submit his application via email.

mahdi3068@gmail.com

Comments