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 bulbouspongesios ; 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)

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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 bulbouspongesios

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 bulbouspongesios

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 ischiocaverenus and bulbospangius 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 ischiocaverenus 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 ischiocaverenus and bulbospangius 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 ischiocaverenus 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 ischiocaverenus 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 ischiocaverenus 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farshad Okhovatian

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

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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

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Person responsible for scientific inquiries

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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 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