

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Saphenous Vein Graft for Treatment of Peyronie's Disease, a Comparison Between Single and Multiple Graft Reconstruction

Protocol summary

Registration timing: **retrospective**

Study aim

we aim to compare two saphenous vein grafting techniques (single- versus multiple) in patients with Peyronie's disease, regarding their success rate and complications.

Design

trial with two groups, without blinding, by simple randomization, and 52 sample size started. After assessing entrance eligibility, we divided every second patient into two groups.

Settings and conduct

this study conducted in Imam-Reza hospital of Mashhad University of Medical Sciences.

Participants/Inclusion and exclusion criteria

fifty-two patients with Peyronie's disease with stable plaque, penile angulation of $>60^\circ$, complex curvature (multiple axis), and without erectile dysfunction who consented to cooperate, included in our study and divided into two groups.

Intervention groups

The first group consists of 26 patients, undergone grafting through a double-Y incision and a single saphenous graft placed within the incision. For the second group, two smaller saphenous vein grafts were placed in the two parallel incisions.

Main outcome variables

penile angulation correction to less than 20 degrees considered success. Patients followed for 18 months, and sacculation, penile shortening, post-operation infection, and penile hypoesthesia assessed as common complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170417033489N6**

Registration date: **2020-12-23, 1399/10/03**

Last update: **2020-12-23, 1399/10/03**

Update count: **0**

Registration date

2020-12-23, 1399/10/03

Registrant information

Name

Salman Soltani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 3802 2553

Email address

soltanis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2011-10-01, 1390/07/09

Expected recruitment end date

2019-01-01, 1397/10/11

Actual recruitment start date

2011-10-01, 1390/07/09

Actual recruitment end date

2019-01-01, 1397/10/11

Trial completion date

2019-01-01, 1397/10/11

Scientific title

Saphenous Vein Graft for Treatment of Peyronie's Disease, a Comparison Between Single and Multiple Graft Reconstruction

Public title

Saphenous Vein Graft for Treatment of Penile Curvature

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

severe penile angulation ($>60^\circ$) penile length less than 13 centimeters hinge- or hourglass-deformity complex curvature (multiple axis) patient's consent to cooperate in this study

Exclusion criteria:

erectile dysfunction

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization, after assessing entrance eligibility, we divided every second patient into two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Azadi sq, Ferdowsi University

City

Mashhad

Province

Razavi Khorasan

Postal code

9117948974

Approval date

2017-02-19, 1395/12/01

Ethics committee reference number

IR.MUMS.FM.REC.1395.589

Health conditions studied

1

Description of health condition studied

Peyronie's disease

ICD-10 code

N48.6

ICD-10 code description

Induration penis plastica

Primary outcomes

1

Description

erectile dysfunction

Timepoint

18 months post operative

Method of measurement

International index of erectile function

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Grafting through a double-Y incision and a single saphenous graft placement. We randomly divided 48 patients into two groups. A single surgical team performed all the surgeries. For both groups, saphenous graft harvested from the thigh's anterior surface, then a circumcision incision performed, and penile skin degloved, then a complete or near-complete penile disassembly was performed (neurovascular bundle and corpus spongiosum). For the first group, one double-Y incision was made on tunica albuginea, and a saphenous graft placed within the incision.

Category

Treatment - Surgery

2

Description

Intervention group: Grafting through two parallel incisions and two pieces of saphenous vein grafts that were placed in the incisions. Two transverse incisions on tunica albuginea were made, and two relatively smaller saphenous grafts were placed. Then the tunica albuginea sutured via 4/0 polydioxanone suture.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam-Reza hospital
Full name of responsible person
Kamyar Tavakkoli Tabassi
Street address
Shariati Sq.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Web page address
<https://medical.mums.ac.ir/manager/2014-02-01-10-43-66/research-deputy>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Kamyar Tavakkoli Tabassi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information related to the International index of erectile function (IIEF) and the presence of common complications like sacculation, penile shortening, post-operation infection, and penile hypoesthesia will be shared.

When the data will become available and for how long

After publication

To whom data/document is available

Scientific and university researchers

Under which criteria data/document could be used

Scientific and university researchers are allowed to ask for the anonymous data of the study. Raw data are provided by the corresponding scientist.

From where data/document is obtainable

Salman Soltani (MD), Postal address: Urology department, Imam Reza hospital, Shariati Square, Mashhad, Iran. Postal code/ P.O. Box: 9137913316
Telephone number: +9851 38022553 Email Address: SoltaniS@mums.ac.ir

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

One week after submitting the request.

Comments