Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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˚, 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**
Registration timing: **retrospective**

Last update: **2020-12-23, 1399/10/03**
Update count: **0**

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

Registrant information

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Salman Soltani

Name of organization / entity
Mashhad 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
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˚) 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
۹۱۷۷۹۴۸۹۷۴
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
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Sponsors / Funding sources

1

Sponsor
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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
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Other areas of specialty/work
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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