

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of local Papaverine on arteriovenous fistula maturation

Protocol summary

Study aim

Objective: Finding a way to increase success rate of native AV fistula maturation is of great value and the aim of this study is to investigate whether Papaverine injection can improve maturation and success rate of AVF.

Design

This study is a clinical randomized trial that involved 110 patients with ESRD, referred for AVF construction. Patients were divided into two equal groups and according to block randomization with random block size;

Settings and conduct

This study was a prospective clinical trial performed in vascular surgery clinic of Imam Reza's hospital of Mashhad university of medical sciences, Mashhad, Iran. The study involved 110 patients with ESRD who referred by nephrologists requiring hemodialysis. For these patients, an arteriovenous fistula was constructed. Patients, an analyzer and a sonographer did not know for which patients papaverin was injected.

Participants/Inclusion and exclusion criteria

The inclusion criteria was: patients with ESRD who need hemodialysis and were suitable for AVF construction in distal upper limbs (snuff box and distal forearm) based on physical examination and Doppler sonography. Exclusion criteria were: diabetic patients, patients with systolic blood pressure <120mm/hg during operation. Previous history of AVF construction on their both upper limbs, allergy to Papaverine.

Intervention groups

0.2-0.4 cc Papaverine (Papaverine Hcl 40mg/ml Exir med Inc.) injected with 30 gauge syringe within the subadventitia of artery and vein after proximal and distal control of artery and vein with bulldogs.

Main outcome variables

maturation time was 37.94 days (SD=11.497) in papaverine group and 44.23 days (SD=9.572) in control group that was statistically significant ($p=0.004$).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171023036953N2**

Registration date: **2017-12-21, 1396/09/30**

Registration timing: **retrospective**

Last update: **2017-12-21, 1396/09/30**

Update count: **0**

Registration date

2017-12-21, 1396/09/30

Registrant information

Name

ALI SABERI

Name of organization / entity

ALAVI hospital of mashhad university

Country

Iran (Islamic Republic of)

Phone

+98 51 3804 7205

Email address

alisaberi.md@gmail.com

Recruitment status

Recruitment complete

Funding source

mashhad university of medical science

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of local Papaverine on arteriovenous fistula maturation

Public title

Effect of local Papaverine on arteriovenous fistula maturation

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: patients with chronic renal failure that are candidate for hemodialysis with appropriate vascular anatomy for AVF creation

Exclusion criteria:

Exclusion criteria were: diabetic patients, patients with systolic blood pressure <120mm/hg during operation. Previous history of AVF construction on their both upper limbs, allergy to Papaverine. Patients put in two equal group (55 patients in each group) matched by age and sex.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

random block

Blinding (investigator's opinion)

Triple blinded

Blinding description

After matching for age and sex, patients were divided into two equal groups and according to block randomization with random block size; they allocated to each group of case or control. This was a triple blind study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Azadi square-Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2012-08-22, 1391/06/01

Ethics committee reference number

IR.MUMS.REC.1391.902

Health conditions studied**1****Description of health condition studied**

RENAL FAILURE

ICD-10 code

N 18.5

ICD-10 code description

RENAL FAILURE

Primary outcomes**1****Description**

Fistula maturation

Timepoint

Weekly for 3 weeks and then monthly for 3 months

Method of measurement

Doppler sonography and physical examination

Secondary outcomes**1****Description**

Vein diameter, venous distance to skin, fistula flow rate

Timepoint

Weekly for 3 weeks and then monthly for 3 months

Method of measurement

Doppler sonography and physical examination

Intervention groups**1****Description**

All patients underwent surgery with the same surgical team and one surgeon. Under local anesthesia with lidocain 1% [Exir Medical Inc., Iran]. We used longitudinal incision about 3-5cm with sharp dissection with minimal manipulation of the vessels. We did

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences

Full name of responsible person

Ali saberi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

alavi hospital

Full name of responsible person

Dr Ali Saberi

Position

vascular surgeryfellowship

Latest degree

Specialist

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available