# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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 stud y 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 sonograhist 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 37.94days (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)
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+98 51 3804 7205
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**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 monthes
**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 monthes
**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 lidocain1 %[ 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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**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 surgeryfelowship
**Latest degree**
Specialist
**Other areas of specialty/work**
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## 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