

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The Effect of Antiplatelet Drugs on the Patency Rate of Arterio-venous Fistulae in Hemodialysis Patients

Protocol summary

Summary

Although Arterio-venous fistulae (AVF) is considered to be vital for chronic kidney disease (CKD) patients, but they may cause complications and problems. For instance they may fail soon after their creation. The most important cause of failure in these cases is intrafistula thrombus formation. Whereas anti-platelet drugs are not routinely used after fistulae creation, we conducted this study to determine the effect of these drugs (aspirin and dipyridamol) on the patency of AVFs. 501 CKD patients who needed hemodialysis were enrolled in the study. 111 patients were excluded by the end of the study due to fail of AVFs function within the first 72 h after the surgery, fail of follow up or drugs disadvantages. These failures are mainly the result of technical problems during the operation. After fistulae creation, they were randomly divided in 3 groups. Each group consisted of 130 patients. The first group received aspirin and the second one received dipyridamol and the third one was the control group that received placebo. We collected all data on age, gender, and underlying disease, site of the AVF (Arterio-venous fistulae), extremity dominancy, and effects of aspirin and dipyridamol on patency rate of the AVF.

General information

Acronym

EDPRF

IRCT registration information

IRCT registration number: **IRCT201009292220N3**

Registration date: **2010-11-06, 1389/08/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-11-06, 1389/08/15

Registrant information

Name

Mohamad Reza Sobhiyeh

Name of organization / entity

Shahid Beheshti University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8001

Email address

mozafar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2003-06-01, 1382/03/11

Expected recruitment end date

2007-10-01, 1386/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Antiplatelet Drugs on the Patency Rate of Arterio-venous Fistulae in Hemodialysis Patients

Public title

The Effect of Drug on the Patency Rate of Fistulae

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All end stage renal disease (ESRD) patients who needed Arterio-venous Fistulae (AVF) for hemodilysis. Exclusion criteria: bleeding tendency, active peptic ulcer disease, pregnancy, lactation, use of

anticoagulant and or non steroidal anti-inflammatory drugs, hepatic insufficiency and history of significant side effects from aspirin or dipyridamol.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **501**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences,
Shahid Beheshti Blv. Daneshjoo Sqr. Velenjak

City

Tehran

Postal code

1985717443

Approval date

2003-06-01, 1382/03/11

Ethics committee reference number

125

Health conditions studied

1

Description of health condition studied

chronic renal failure

ICD-10 code

N18.0

ICD-10 code description

End-stage renal disease

Primary outcomes

1

Description

patency of Arterio-venous fistulae according age ,sex ,site

Timepoint

weekly

Method of measurement

presense or absence Thrill or bruit

Secondary outcomes

empty

Intervention groups

1

Description

75 milligram /day Dipyridamol after creation arterio-venous fistulae

Category

Prevention

2

Description

325 milligram /day Aspirin after creation arterio-venous fistulae

Category

Prevention

3

Description

multi vitamin tablet after creation arterio-venous fistulae

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Surgery, Shohada e Tajrish Hospital

Full name of responsible person

mohsen rozrokh-mohamad reza sobhiyeh

Street address

Department of Surgery,Shohada e Tajrish
Hospital,Tajrish Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Dr.M.Rahmati Rudsari

Street address

Vice-Chancellor for Research, 5th floor, 2nd block,
Shahid Beheshti University of Medical
Science,Velenjak

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellor for Research, Shahid Beheshti University
of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohamad Reza Sobhiyeh

Position

General Surgen

Other areas of specialty/work

Street address

Department of Surgery, Shohada e Tajrish
Hospital,Tajrish Square

City

Tehran

Postal code

1989934148

Phone

+98 21 2271 8000

Fax

+98 21 2272 1144

Email

mreza_sobhiyeh@yahoo.com , mozafar@sbmu.ac.ir

Web page address

sbmu.ac.ir

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohsen Rouzrokh

Position

Associated Professor of Pediatric Surgery

Other areas of specialty/work

Street address

Pediatric Surgery Research Center, Mofid Children's
Hospital

City

Tehran

Postal code

1546815514

Phone

+98 21 2222 7021

Fax

+98 21 2292 4489

Email

mohsen_rouzrokh@yahoo.com

Web page address

sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohamad Reza Sobhiyeh

Position

General Surgen

Other areas of specialty/work

Street address

Department of Surgery, Shohada e Tajrish
Hospital,Tajrish Square

City

Tehran

Postal code

1989934148

Phone

+98 21 2271 8000

Fax

+98 21 2272 1144

Email

mreza_sobhiyeh@yahoo.com , mozafar@sbmu.ac.ir

Web page address

sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty