

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Investigation of intravenous dexmedetomidine administration effect on patency of arteriovenous fistula in patients undergoing arteriovenous fistula creation surgery

Protocol summary

Study aim

Investigation of intravenous dexmedetomidine administration effect on patency of arteriovenous fistula in patients undergoing arteriovenous fistula creation surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 4 on 50 patients. Block randomization method was used for randomization.

Settings and conduct

Patients with dialysis-dependent renal failure referred to Qom Shahid Beheshti Hospital who are candidates for arteriovenous fistula surgery by a single surgeon will be studied. The drug or placebo is prepared by a person out of study. Clinical caregiver (anesthesia technician), patient, researcher, outcome assessor and surgeon do not know the contents of the syringe, and after completing the information and consequences, the main nature of the substance is told to the researcher and recorded.

Participants/Inclusion and exclusion criteria

With respect to the role of factors such as heart failure, smoking and age over 80 years in fistula patency, in order to eliminate the confounding effects patients with renal failure dependent on dialysis and candidate for arteriovenous fistula surgery that have not listed conditions, are included in the study.

Intervention groups

In the intervention group, patients will receive a bolus injection of 1 microgram per kilogram ($\mu\text{g/kg}$) of dexmedetomidine for 10 minutes with monitoring of oxygen saturation, blood pressure and electrocardiogram, and then infused with dexmedetomidine at a concentration of 0.5 ($\mu\text{g/kg}$) per hour. In control group, patients will receive a placebo (normal saline) injection in the same way.

Main outcome variables

Postoperative arteriovenous fistula patency rate, surgeon satisfaction, intraoperative sedation, intraoperative analgesia, demographic information (age, sex and body mass index), underlying diseases and vital signs during surgery (pulse, blood pressure and oxygen saturation)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210807052098N1**

Registration date: **2021-10-19, 1400/07/27**

Registration timing: **prospective**

Last update: **2021-10-19, 1400/07/27**

Update count: **0**

Registration date

2021-10-19, 1400/07/27

Registrant information

Name

Mohammad Reza Hoseini Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 25 3773 9765

Email address

hoseini.amini@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of intravenous dexmedetomidine administration effect on patency of arteriovenous fistula in patients undergoing arteriovenous fistula creation surgery

Public title

Investigation of intravenous dexmedetomidine administration effect on patency of arteriovenous fistula in patients undergoing arteriovenous fistula creation surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with renal failure and dependent on dialysis candidate for arteriovenous fistula surgery without heart failure non smoker age below eighty years

Exclusion criteria:

The patient's unwillingness to participate in the study at any time during the study Contraindications for the use of dexmedetomidine: severe heart block, severe bradycardia, severe heart failure, QT changes, hypotension, liver failure, intravascular volume depletion, allergy to alpha 2 agonists smoking age over 80 years heart failure

AgeFrom **18 years** old to **80 years** old**Gender**

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be randomly assigned to the treatment(A) and control(B) groups. The allocation of individuals will be done by block randomization method. Block size will be considered four numbers. So we have six quadruple blocks consisting of BAAB.ABBA.BABA, BBAA, ABAB, AABB. The selection of each block is also random and is done using dice. For example, if the number 3 is rolled, the BBAA block is considered. So the first two patients are assigned to control (B) and the next two patients to treatment (A). The dice are thrown 26 times to complete the assignment of patients to treatment groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug or placebo is prepared by a person who does not know the details of the study in the infusion syringes and half of patients will randomly receive drug and half placebo. Clinical caregiver (anesthesia technician), patient, researcher, outcome assessor and surgeon do not know the contents of the syringe, and after completing the information and consequences, the main nature of the substance is told to the researcher and recorded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Qom University of Medical Sciences

Street address

No 62, 30th alley, Doreshahr st, Qom

City

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Province

Ghoum

Postal code

3715668349

Approval date

2021-07-14, 1400/04/23

Ethics committee reference number

IR.MUQ.REC.1400.078

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

renal failure

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

dexmedetomidine

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

arteriovenous fistula

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

patency rate of arteriovenous fistula

Timepoint

after surgery and one month later

Method of measurement

clinical examination by surgeon

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 1 µg per kg body weight of dexmedetomidine over ten min and then infusion of dexmedetomidine at a concentration of 0.5 µg / kg per hour

Category

Treatment - Drugs

2

Description

Control group: Bolus injection of normal saline and then infusion of normal saline as in the intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mohammad Reza Hoseini Amini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

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

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Mohammad Reza Hoseini Amini

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available