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 (µg/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 (µg/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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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
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target 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
Qom
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
Ghoum 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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Mohammad Reza Hoseini Amini
Position
resident
Latest degree
Medical doctor
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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