

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparison of the sedative effect of Remifentanil and Dexmedetomidine in patients undergoing venous arterial fistula implantation

Protocol summary

Study aim

Comparison of the sedative effect of Remifentanil and Dexmedetomidine in patients undergoing venous arterial fistula implantation

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 will be performed on 32 patients. Excel software rand function will be used for randomization.

Settings and conduct

In the operating room, the severity of pain in patients will be determined before surgery and based on the Visual Analogue Scale (VAS) system. Both patients and anesthesiologists will be completely unaware of the nature of prescription vials. So the vials will be covered with foil. Then, the intensity of postoperative pain will be measured based on the VAS at the moment after surgery in the operating room and also every half hour, up to two hours after surgery in the recovery and surgery ward.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age group 19 to 60 years - Patients with stable hemodynamic status Exclusion criteria: 1) Patients with a history of cardiovascular abnormalities, 2) Patients with a history of chronic diseases such as liver disorders, 3) Patients with a history of allergies to anesthetics, including opioids, 4) Patients with a history of use Opium, 5) Pregnant or lactating women, 6) Recent respiratory tract infection, 7) Severe bronchopulmonary disease

Intervention groups

One group will be received Dexmedetomidine (bolus dose of 0.4 µg / kg intravenously over 10 minutes and maintenance dose of 0.5 to 1.00 µg / kg / min) and the other group will be received Remifentanil (bolus dose of 0.5 µg / kg). Intravenously over 10 minutes and a maintenance dose of 0.5 to 0.25 micrograms per kilogram per minute.

Main outcome variables

Pain score Requires opioid administration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200502047269N1**

Registration date: **2020-11-26, 1399/09/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-26, 1399/09/06**

Update count: **0**

Registration date

2020-11-26, 1399/09/06

Registrant information

Name

Alireza Maleki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 1112

Email address

dr.alireza_maleki@irimed.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the sedative effect of Remifentanil and Dexmidetomidine in patients undergoing venous arterial fistula implantation

Public title

Comparison of the sedative effect of Remifentanil and Dexmidetomidine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age group 19 to 60 years Patients with stable hemodynamic status

Exclusion criteria:

Patients with a history of cardiovascular abnormalities
Patients with a history of chronic diseases such as liver disease
Patients with a history of allergies to anesthetics, including opioids
Patients with a history of opium use
Pregnant or lactating women
Recent respiratory tract infection
Severe bronchopulmonary disease

Age

From **19 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups by permuted block randomization. The size of the blocks will randomly include 4 and 6 blocks, in each block, two and three participants will be equally placed in each of the intervention and control groups, respectively. One group receiving dexmedetomidine (bolus dose of 0.5 µg / kg intravenously over 10 minutes and maintenance dose of 0.5 to 1.00 µg / kg / min) or remifentanil (bolus dose of 0.5 µg / kg) Intravenously for 10 minutes at a maintenance dose of 0.5 to 0.25 µg / kg / min.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both patients and anesthesiologists will be completely unaware of the nature of prescription vials. For this purpose, vials will be covered with foil. Patients will be informed that they are participating in a research study but are not aware of the type of group assigned.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Firoozgar Hospital, Beh Afarin St., Karim Khan St., Valiasr Sq., Tehran

City

Tehran

Province

Tehran

Postal code

۱۵۹۳۷۴۷۸۱۱

Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.IUMS.FMD.REC.1399.115

Health conditions studied

1

Description of health condition studied

Patients undergoing venous arterial fistula implantation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score

Timepoint

At the moment after the operation and also every half an hour, up to two hours after the operation

Method of measurement

Use of Visual Analogue Scale (VAS) scoring system

Secondary outcomes

1

Description

Nausea and vomiting

Timepoint

After surgery

Method of measurement

Observation

2

Description

Hypertension

Timepoint

After surgery

Method of measurement

Mercury barometer

3

Description

Oxygen saturation

Timepoint

After surgery

Method of measurement

Pulse oximetry

4

Description

Tachycardia and bradycardia

Timepoint

After surgery

Method of measurement

Monitoring

Intervention groups

1

Description

Intervention group 1: Dexamidomethidine administration (bolus dose of 0.4 µg / kg intravenously over 10 minutes and maintenance dose of 0.5 to 1.00 µg / kg / min). Its manufacturer is Exir Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Intervention group 2: Remifentanil administration (bolus dose of 0.5 µg / kg intravenously over 10 minutes and maintenance dose of 0.5 to 0.25 µg / kg / min). Its manufacturer is Exir Pharmaceutical Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hasheminejad Hospital

Full name of responsible person

Alireza Maleki

Street address

Hasheminejad Hospital, Valinejad street, Valiasr Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.seyed-Abbas Motevallian

Street address

Hemmat Highway next to Milad Tower, Iran University of Medical Sciences, Tehran

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Alireza Maleki

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Use the resulting information by referring to it

From where data/document is obtainable

Dr. Alireza Maleki, Firoozgar Hospital, Beh Afarin St., Karim Khan St., Valiasr Sq., Tehran-
Dr.alireza_maleki@irimed.org

What processes are involved for a request to access data/document

Submit your request via email to

Dr.alireza_maleki@irimed.org. Your reply will be given within three days.

Comments