Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

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

Protocol summary

Study aim
Comparison of the sedative effect of Remifentanil and Dexmidetomidine 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 Dexamidomethidine (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

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Iran (Islamic Republic of)

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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 dexamidomethidine (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
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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
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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
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
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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