Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the Effect of Adding Dexmedetomidine, Ketamine, Neostigmine and Magnesium Sulfate to Rupivacaine inmanagment of pain and Hemodynamic Changes in intravenous regional anesthesia of distal radius surgery

Protocol summary

Study aim
Comparison of the effect of Adding Dexmedetomidine, Ketamine, Neostigmine and Magnesium Sulfate to Rupivacaine on pain and hemodynamic changes in intravenous regional anesthesia during distal radius surgery

Design
This study is clinical trial and double blind.150 patients candidate forearm surgery in Valiasr hospital will inter this study.We will divide patients in 5 groups by simple randomization.Groups are parallel.

Settings and conduct
150 patients candidate for forearm surgery at Valiasr hospital will inter the study.This study is double blind. Outcome assessor and analyzer will not be aware of grouping. Codes of group are available to analyzer and outcome assessor. We record blood pressure, heart rate, oxygen saturation, pain, opioid use and duration of motor and sensory block in each group.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Candidate for forearm Surgery; ASA class I and II; Being at the age of 20-65 years old. Exclusion criteria:Duration of surgery less than 30 minutes and more than 90 minutes; localized intravenous anesthetics termination during surgery for any reason; Reinoids disease; Sickle cell anemia; history of allergy to drugs

Intervention groups
We will inject 0.5 micro gram per kilogram Dexmedetomidine (Exir.co .Iran) in first intervention group and 1 milligram per kilogram Ketamine (Rotexmod .Germany) in second intervention group and 500 micro gram Neostigmin (Caspian.Co.Iran) in third intervention group and 10 milligram Magnesium Sulfate 50 % (Shahid ghazi Tabriz.Co.Iran) in forth intervention group. We Will inject Rupivacaine 0.2 (Molteni .Co.Italia) for participants in all groups. We Will inject 35 milliliter of Rupivacaine 0.2 and 5 milliliter normal saline in control group.

Main outcome variables
blood pressure; heart rate; oxygen saturation; pain; motor and sensory block duration; opioid usage rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N113**
Registration date: **2019-06-12, 1398/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-12, 1398/03/22**
Update count: **0**

Registration date
2019-06-12, 1398/03/22

Registrant information

Name
Fariba Farokhi
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 86 3222 2003
Email address
f.farokhi@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-06, 1397/12/15
Expected recruitment end date
2020-03-05, 1398/12/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of Adding Dexmedetomidine, Ketamine, Neostigmine and Magnesium Sulfate to Rupivacaine inmanagment of pain and Hemodynamic Changes in intravenous regional anesthesia of distal radius surgery

Public title
The effect of drug anesthesia on pain and hemodynamic changes during intravenous regional anesthesia of distal radius surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
candidate for forearm Surgery ASA class I and II Being at the age of 20-65 years old
Exclusion criteria:
Duration of surgery less than 30 minutes and more than 90 minutes localized intravenous anesthetics termination during surgery for any reason Reinoids disease Sickle cell anemia history of allergy to drugs using drugs and psychotropic substances There is more than a fracture in the body or surgery
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individual randomization with random number table in division of groups into 5 groups of A and B and C and D and E. Randomization method: Simple randomization. Random unit: Individual. How to build sequences: We set the framework for our statistical society in first. We started from a table point in a row or column. Given the type of code in the row, we chose the same number of digits. After that, the numbers control the path. It is unnecessary to deal with two numbers, one of which is smaller and the other is larger than the population size. We noticed smaller numbers of the statistical community. We have to continue this work so that the number of samples is completed. Even numbers will be used for intervention group and odd numbers will be used for the control group. Allocation concealment: Numbered drug containers
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind).Outcome assessor and analyzer don't aware from grouping.The person evaluating the outcome is unaware of the grouping. Groups A and B and C and D and E are available for analyzer and outcome assessor.The syringe containing the drugs are covered and labeled as A and B and C and D and E at the discretion of anesthesiology residents
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Arak University Of Medical Sciences
Street address
Dr Mohammad Rafiei, Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
38149578558
Approval date
2019-02-24, 1397/12/05
Ethics committee reference number
IR.ARAKMU.REC.1397.347

Health conditions studied

1

Description of health condition studied
Forearm surgery
ICD-10 code
S52.9
ICD-10 code description
Fracture of forearm, part unspecified

Primary outcomes

1

Description
Mean arterial blood pressure
Timepoint
Before starting tourniquet, 5, 10, 15, 20, 30, 40 minutes after start of surgery, and then every 10 minutes after emptying the tourniquet and recovery
Method of measurement
Barometer

2

Description
Heart rate
Timepoint
Before starting tourniquet, 5, 10, 15, 20, 30, 40 minutes after start of surgery, and then every 10 minutes after emptying the tourniquet and recovery
Method of measurement
Count

3

Description
Percent of oxygen saturation
Timepoint
Before starting tourniquet, 5, 10, 15, 20, 30, 40 minutes after start of surgery, and then every 10 minutes after emptying the tourniquet and recovery
Method of measurement
Pulse oximetry

4

Description
Duration of motor block
Timepoint
Every 5 minute
Method of measurement
Minute

5

Description
Duration of Sensory block
Timepoint
Every 1minute
Method of measurement
Minute

6

Description
Pain
Timepoint
After filling the tourniquet, at the time of 15, 30 and 45 and every 15 minutes to end of surgery
Method of measurement
Visual Analogue Scale Questionnaire

7

Description
mean of narcotic
Timepoint
24 hour after surgery
Method of measurement
Milligram

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: We will inject 0.5 micro gram in kilogram Dexmedetomidine (Exir.co .Iran) plus Rupivacaine 0.2 (Molteni .Co.Italia) in first group.
Category
Treatment - Drugs

2

Description
Intervention group 2: We will inject 1 milligram in kilogram Ketamine (Rotexmod .Germany)plus Rupivacaine 0.2 (Molteni .Co.Italia) in second group
Category
Treatment - Drugs

3

Description
Intervention group3: We will inject 500 micro gram Neostigmin (Caspian.Co.Iran)plus Rupivacaine 0.2 (Molteni .Co.Italia) in third group
Category
Treatment - Drugs

4

Description
Intervention group4: We will inject 10 milligram Magnesium Sulfate 50 % (Shahid ghazi Tabriz.Co.Iran) plus Rupivacaine 0.2 (Molteni .Co.Italia) in forth group
Category
Treatment - Drugs

5

Description
Control group: We Will inject 35 millliliter of Rupivacaine 0.2 and 5 milliliter normal saline in control group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital

Full name of responsible person
Dr Bijan Yazdi
Street address
Valiasr hospital, Valiasr squre
City
Arak
Province
Markazi
Postal code
38149578558
Phone
+98 86 3222 2003
Email
yazdi@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Arjmandzadegan
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
38149578558
Phone
+98 86 3417 3638
Email
arjmandzadegan@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr Esmaeel Moshiri
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Shirodi street, Valiasr square, Valiasr hospital
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
modir.he@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
dr Bijan Yazdi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
yazdi@arakmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Amirreza Modir
Position
Medicine student
Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Email

modir@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Yazdi

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

They have to write letters to the professors and the university

Comments