

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effect of Adding Dexmedetomidine, Ketamine, Neostigmine and Magnesium Sulfate to Rupivacaine in management 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 enter 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 enter 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; Reinolds 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)

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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 in management 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 Reinolds disease Sick 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 square, Sardasht, Arak

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Province

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Postal code

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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 milliliter 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

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Valiasr hospital, Valiasr squire

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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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

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

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Medicine student

Latest degree

A Level or less

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

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