

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the effect of adding midazolam, paracetamol, tramadol and magnesium sulphate to ropivacaine in reducing pain and hemodynamic changes in intravenous local anesthesia

Protocol summary

Study aim

Comparison of the effect of adding midazolam, paracetamol, tramadol and magnesium sulphate to ropivacaine in reducing pain and hemodynamic changes in intravenous local anesthesia

Design

The study will be double blind and clinical trial. 160 patients will be randomly divided into 5 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Patients candidate for forearm surgery in Valiasr Hospital in Arak are divided into 5 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: no history of allergy to the drugs used in the study, no more than one fracture in the body or surgery, absence of neurological disorders in the hand
Exclusion criteria: For any reason, local intravenous anesthesia may be terminated during surgery, not consent to participate in study

Intervention groups

Intervention group 1: 50 milligram in kilogram of magnesium sulfate 50% made by Shahid Ghazi Pharmaceutical Company of Tabriz with ropivacaine two tenths of a percent will inject. Intervention group 2: 200 milligram of paracetamol made by Tehran Shimi Company with Ropivacaine two tenths of a percent will inject. Intervention group 3: 100 mg of tramadol made by Caspian Tamin Rasht Company - Iran with Ropivacaine two tenths of a percent will inject. Intervention group 4: 50 micro gram in kilogram midazolam made by Caspian Tamin Rasht - Iran with Ropivacaine two tenths of a percent will inject. Control group: 5 ml of normal saline with 35 ml of ropivacaine two tenths of a percent with a total volume of 40 ml will

be injected intravenously.

Main outcome variables

Duration of sensory and motor block, pain, average use opioids

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N168**

Registration date: **2021-11-05, 1400/08/14**

Registration timing: **prospective**

Last update: **2021-11-05, 1400/08/14**

Update count: **0**

Registration date

2021-11-05, 1400/08/14

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

2021-11-22, 1400/09/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of adding midazolam, paracetamol, tramadol and magnesium sulphate to ropivacaine in reducing pain and hemodynamic changes in intravenous local anesthesia

Public title

Comparison of the effect of adding midazolam, paracetamol, tramadol and magnesium sulphate to ropivacaine in reducing pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate of forearm surgery ASA class 1 and 2 No Raynaud's disease Absence of any vascular disease No sickle cell anemia No history of allergy to the drugs used in the study Lack of cyanosis of the affected limb Do not use drugs and psychotropic substances No contraindication to intravenous anesthesia No more than one fracture in the body or surgery Absence of chronic pain syndrome Absence of neurological disorders in the hand

Exclusion criteria:

For any reason, local intravenous anesthesia may be terminated during surgery Not consent to participate in study Duration of operation less than 30 minutes or more than 90 minutes

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into 5 groups using a permuted balanced block randomization method with the size of blocks 3 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)

Double blinded

Blinding description

It is a double-blind study. Analysts, evaluators, and

participants are unaware of the grouping. The intern is unaware of the drugs prescribed in each group and the anesthesiologist prepares the drugs and provides them to the intern, and the patients are not aware of their group.

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

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

City

Arak

Province

Markazi

Postal code

848176941

Approval date

2021-10-10, 1400/07/18

Ethics committee reference number

IR.ARAKMU.REC.1400.173

Health conditions studied**1****Description of health condition studied**

Forearm surgery

ICD-10 code

S55.001S

ICD-10 code description

Unspecified injury of ulnar artery at forearm level, right arm, sequela

Primary outcomes**1****Description**

Sensory block

Timepoint

From the beginning study to 24 hours

Method of measurement

Physical examination

2**Description**

Motor block
Timepoint
From the beginning study to 24 hours
Method of measurement
Physical examination

3

Description
Pain
Timepoint
After filling the tourniquet, 15, 30 and 45 minutes after the start of surgery and 30, 60, 90 and 120 minutes after the end of surgery
Method of measurement
Visual analogue pain questionnaire

4

Description
Average use opioids
Timepoint
Within 24 hours after surgery
Method of measurement
View file

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: 50 milligram in kilogram of magnesium sulfate 50% made by Shahid Ghazi Pharmaceutical Company of Tabriz with rupivacaine two tenths of a percent will inject.
Category
Treatment - Drugs

2

Description
Intervention group 2: 200 milligram of paracetamol made by Tehran Shimi Company with Rupivacaine two tenths of a percent will inject.
Category
Treatment - Drugs

3

Description
Intervention group 3: 100 mg of tramadol made by Caspian Tamin Rasht Company - Iran with Rupivacaine two tenths of a percent will inject.
Category
Treatment - Drugs

4

Description

Intervention group 4: 50 micro gram in kilogram midazolam made by Caspian Tamin Rasht - Iran with Rupivacaine two tenths of a percent will inject.
Category
Treatment - Drugs

5

Description
Control group: 5 ml of normal saline with 35 ml of rupivacaine two tenths of a percent with a total volume of 40 ml will be injected intravenously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr Hesamodin Modir
Street address
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3848176941
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
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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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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