

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of onset, duration and quality of supraclavicular block using 0.5% bupivacaine with magnesium sulphate , ketamine and neostigmine in forearm orthopedic surgery

Protocol summary

Study aim

Comparison of onset, duration and quality of supraclavicular block using 0.5% bupivacaine with magnesium sulphate , ketamine and neostigmine in forearm orthopedic surgery

Design

The study will be double blind and clinical trial. 90 patients will be randomly divided into 3 groups. The groups will be parallel. The trial phase will be 3.

Settings and conduct

Candidates forearm orthopedic surgery in Valiasr Hospital in Arak are divided into 3 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: 20 -70 years ,candidate for upper limb orthopedic surgery ,no more than one fracture in the body or surgery ,no blood coagulation diseases and disorders in PTT, PT and INR ,body mass index less than 35 ,lack of psychological problems ,no pregnant ,absence of neurological disorders in the hand ,no allergies to drugs used ,absence of chronic pain syndrome
Exclusion criteria: Lack of patient cooperation to perform the block ,block failure ,surgery time less than 50 and more than 150 minutes ,need for more sedation than stated in the plan

Intervention groups

Intervention group 1: 25 milliliter of 0.5% bupivacaine with 100 milligram of magnesium sulfate (1 millilite of 10% solution) is prescribed. (Bupivacaine by Strazenka UK-Magnesium Sulfate by Shahid Ghazi Co in Tabriz)
Intervention group: 25millilite of bupivacaine 0.5% with 2 milligram in kilogram of ketamine is prescribed. (Ketamine made by Rotex Medica - Germany)
Intervention group 3: 25 millilite of 0.5% bupivacaine with 500 micrograms of neostigmine is prescribed.

(Neostigmine ampoule made by Caspian Tamin Co - Rasht)

Main outcome variables

Pain, narcotics consumption, sensory block, motor block

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N158**

Registration date: **2021-05-11, 1400/02/21**

Registration timing: **prospective**

Last update: **2021-05-11, 1400/02/21**

Update count: **0**

Registration date

2021-05-11, 1400/02/21

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

2021-05-22, 1400/03/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of onset, duration and quality of supraclavicular block using 0.5% bupivacaine with magnesium sulphate , ketamine and neostigmine in forearm orthopedic surgery

Public title

Comparison of onset, duration and quality of supraclavicular block using 0.5% bupivacaine with magnesium sulphate , ketamine and neostigmine in forearm orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

20 -70 years Candidate for upper limb orthopedic surgery No more than one fracture in the body or surgery No blood coagulation diseases and disorders in PTT, PT and INR Body mass index less than 35 Lack of psychological problems No pregnant Absence of neurological disorders in the hand No allergies to drugs used Absence of chronic pain syndrome

Exclusion criteria:

Lack of patient cooperation to perform the block Block failure Surgery time less than 50 and more than 150 minutes Need for more sedation than stated in the plan

AgeFrom **20 years** old to **70 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple individual randomization with random allocation with envelopes in 3 groups A and B and C. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

Outcome assessor and data analyzer and participant are blind (double blind). Outcome assessor and data analyzer and participant don't aware from grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2021-04-21, 1400/02/01

Ethics committee reference number

IR.ARAKMU.REC.1400.001

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

Forearm orthopedic surgery

ICD-10 code

S52.9

ICD-10 code description

Unspecified fracture of forearm

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

Pain

Timepoint

In recovery and 2 ,4, 8, 12 and 24 hours after surgery

Method of measurement

Visual analog scale of pain

2**Description**

Narcotics consumption

Timepoint

24 hours after surgery

Method of measurement

Observation

3**Description**

Sensory block

Timepoint

Every 1 minute

Method of measurement

chronometer

4**Description**

Motor block

Timepoint

Every 5 minute

Method of measurement

chronometer

Secondary outcomes

empty

Intervention groups**1****Description**

ntervention group 1: 25 milliliter of 0.5% bupivacaine with 100 milligram of magnesium sulfate (1 millilite of 10% solution) is prescribed. (Bupivacaine by Strazenka UK-Magnesium Sulfate by Shahid Ghazi Co in Tabriz)

Category

Treatment - Drugs

2**Description**

Intervention group 2: 25millilite of bupivacaine 0.5% with 2 milligram in kilogram of ketamine is prescribed. (Ketamine made by Rotex Medica - Germany)

Category

Treatment - Drugs

3**Description**

Intervention group 3:25 millilite of 0.5% bupivacaine with 500 micrograms of neostigmine is prescribed. (Neostigmine ampoule made by Caspian Tamin Co - Rasht)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr Esmaeel Moshiri

Street address

Valiasr hospital, Valiasr squire

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Email

moshiri@gmail.com

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

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Street address

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

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

alikamaliir@yahoo.com

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 Bijan Yazdi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr Hospital, Valiasr square, 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 scientific 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 updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Habib Nadimi Bojnedi

Position

medicine student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

habibnadimi.kobib@gmail.com

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