

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison onset,duration and quality of axillary block with ropivacaine 0.5% plus dexmedetomidine and fentanyl and Verapamil in forearm surgeries

Protocol summary

Study aim

Comparison onset,duration and quality of axillary block with ropivacaine 0.5% plus dexmedetomidine and fentanyl and Verapamil in forearm surgeries

Design

This study is clinical trial and double blind.105 patients candidate forearm surgery in Valiasr hospital will inter this study. We will divide patients in 3 groups by simple randomization. Groups are parallel.

Settings and conduct

This study is clinical trial and double blind.105 patients candidate forearm surgery in Valiasr hospital will inter this study. Outcome assessor and analyzer not aware from grouping. Codes of group are available to analyzer and outcome assessor.

Participants/Inclusion and exclusion criteria

Inclusion criteria:20 to 70 years, fracture of the forearm and hand, absence more than a fracture in the body or surgery, body mass index less than 35, not having blood coagulation and disorder PTT and PT and INR, lack of psychological problems, no pregnancy, absence of neurological disorders in the hand Exclusion criteria: Failure to cooperate with the patient to perform the block, allergy to drug, infection in block area, surgical time more than 150 minutes, block failure

Intervention groups

First group: We inject 40 milliliter of Ropivacaine 0.5 % plus 1 micro gram in kilogram Dexmedetomidine. Second group:We inject 40 milliliter of Ropivacaine 0.5 % plus 1 micro gram in kilogram Fentanyl. Third group:We inject 40 milliliter of Ropivacaine 0.5 % plus 2.5 milligram Verapamil in kilogram Dexmedetomidine.

Main outcome variables

blood pressure, heart rate, oxygen saturation, pain, duration motor and sensory block, drug consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N111**

Registration date: **2019-05-09, 1398/02/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-09, 1398/02/19**

Update count: **0**

Registration date

2019-05-09, 1398/02/19

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

2019-01-21, 1397/11/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison onset,duration and quality of axillary block with ropivacaine 0.5% plus dexmedetomidine and fentanyl and Verapamil in forearm surgeries

Public title

Comparison onset,duration and quality of axillary block with ropivacaine 0.5% plus dexmedetomidine and fentanyl and Verapamil in forearm surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

20 to 70 years Fracture of the forearm and hand Absence more than a fracture in the body or surgery Body mass index less than 35 Not having blood coagulation and disorder PTT and PT and INR Lack of psychological problems No pregnancy Absence of neurological disorders in the hand

Exclusion criteria:

Failure to cooperate with the patient to perform the block Allergy to drug Infection in block area Surgical time more than 150 minutes Block failure

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random number table in division of groups in two groups A and B and C. Randomization method: Simple randomization. Random unit: Individual. How to build sequences: First, we set the framework for our statistical society. 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. We noticed smaller numbers of the statistical community. We have to continue this work so that the number of samples is completed. Even numbers were used for intervention group and odd numbers were 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 are available to analyzer and outcome assessor. The syringe containing

the drugs are covered and labeled as A and B and C at the discretion of anesthesiology residents.

Placebo

Not 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

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

38149578558

Approval date

2018-12-30, 1397/10/09

Ethics committee reference number

IR.ARAKMU.REC.1397.266

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

Duration of motor block

Timepoint

Every 5 minute

Method of measurement

Minute

2

Description

Duration of Sensory block

Timepoint

Every 1minute

Method of measurement

Minute

3

Description

Pain

Timepoint

Recovery and 2, 4, 8, 12, and 24 hours after surgery

Method of measurement

Visual Analogue Scale Questionnaire

4

Description

Mean of narcotic

Timepoint

24 hour after surgery

Method of measurement

Milligram

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We inject 40 milliliter of Ropivacaine 0.5 % (Molteni .Co.Italia) plus 1 micro gram in kilogram Dexmedetomidine(Exir.co .Iran).

Category

Treatment - Drugs

2

Description

Intervention group: We inject 40 milliliter of Ropivacaine 0.5 % (Molteni .Co.Italia) plus 1 micro gram in kilogram Fentanyl.

Category

Treatment - Drugs

3

Description

Intervention group: We inject 40 milliliter of Ropivacaine 0.5 % (Molteni .Co.Italia) plus 2.5 milligram Verapamil in kilogram Dexmedetomidine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Hesamodin Modir

Street address

Valiasr hospital, Valiasr squire

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3848176941

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modir.he@gmail.com

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

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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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Nazanin hashemi

Position

Medicine student

Latest degree

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General Practitioner

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Dr Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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

Arak University of Medical Sciences

Full name of responsible person**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 Modir

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

They have to write letters to the professors and the university

Comments