

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of adding Dexmedetomidine, Granisetron and Nitroglycerin to Rupivacaine in Reducing Pain and Hemodynamic Changes in intravenous regional anesthesia of forearm surgery

Protocol summary

Study aim

Comparison of the effect of adding Dexmedetomidine, Granisetron and Nitroglycerin to Rupivacaine in Reducing Pain and Hemodynamic Changes in intravenous regional anesthesia of forearm surgery

Design

This study is clinical trial and double blind. patients will be divided in 4 groups by simple randomization.Groups are parallel.

Settings and conduct

Patients candidate for forearm surgery in Valiasr hospital in Arak will enter this study. This study is double blind. Researcher who complete questionnaire and analyzer and participant are blind (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria:Both of gender, 20 to 65 years, candidate forearm surgery, ASA class I and II Exclusion criteria: Rinod's disease, sickle cell anemia, history of allergy to the drugs used in the study, affected limb cyanosis, drugs and psychotropic use, there is more than one body fracture or surgery, pregnancy, chronic pain, syndrome neurological disorders in the hand, hypertension-related disease and heart erythema and heart failure

Intervention groups

Dexmedetomidine group:we will inject 0/5 micro gram in kilogram co.Dexmedetomidine (Exir Co.Iran) plus 35 milliliter Rupivacaine 0/2%(Molteni Co.Italia) Granisetron group: we will inject 2 milligram Granisetron(Caspian Co.Iran) plus 35 milliliter Rupivacaine 0/2%(Molteni Co.Italia) Nitroglycerin group: we will inject 200 micro gram Nitroglycerin (Caspian Co.Iran) plus 35 milliliter Rupivacaine 0/2%(Molteni Co.Italia) Control group: we will inject 5 milliliter normal saline plus 35 milliliter Rupivacaine 0/2%(Molteni Co.Italia)

Main outcome variables

Sensory block duration, motor block duration, mean drug

use, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N123**

Registration date: **2019-11-02, 1398/08/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-02, 1398/08/11**

Update count: **0**

Registration date

2019-11-02, 1398/08/11

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

2019-07-23, 1398/05/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of adding Dexmedetomidine, Granisetron and Nitroglycerin to Rupivacaine in Reducing Pain and Hemodynamic Changes in intravenous regional anesthesia of forearm surgery

Public title
Comparison of the effect of adding Dexmedetomidine, Granisetron and Nitroglycerin to Rupivacaine in Reducing Pain and Hemodynamic Changes in intravenous regional anesthesia of forearm surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Both of gender 20 to 65 years Candidate forearm surgery ASA class I and II
Exclusion criteria:
Rinod's disease Sickle cell anemia History of allergy to the drugs used in the study Affected limb cyanosis Drugs and psychotropic use There is more than one body fracture or surgery Pregnancy Chronic pain syndrome Neurological disorders in the hand Hypertension-related disease and heart erythema and heart failure

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: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with randomization with envelopes in two 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
This study is double blind. Researcher who complete questionnaire and analyzer and participant 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.

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
2019-07-21, 1398/04/30

Ethics committee reference number
IR.ARAKMU.REC.1398.112

Health conditions studied

1

Description of health condition studied
forearm surgery

ICD-10 code
S52.9

ICD-10 code description
Unspecified fracture of forearm

Primary outcomes

1

Description
Duration of motor block

Timepoint
Every 5 minute

Method of measurement
Minute

2

Description
Duration of Sensory block

Timepoint
Every 1 minute

Method of measurement
Minute

3

Description

Pain

Timepoint

After filling the tourniquet, at the time of 15, 30 and 45 and every 15 minutes until the end of surgery

Method of measurement

Visual Analogue Scale Questionnaire

4

Description

Mean use of narcotic

Timepoint

24 hour after surgery

Method of measurement

Milligram

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We will inject 0/5 micro gram in kilogram co.Dexmedetomidine (Exir Co.Iran) plus 35 milliliter Rupivacaine 0/2%(Molteni Co.Italia).

Category

Treatment - Drugs

2

Description

Intervention group: we will inject 2 milligram Granisetron(Caspian Co.Iran) plus 35 milliliter Rupivacaine 0/2%(Molteni Co.Italia).

Category

Treatment - Drugs

3

Description

Intervention group: We will inject 200 micro gram Nitroglycerin (Caspian Co.Iran) plus 35 milliliter Rupivacaine 0/2%(Molteni Co.Italia)

Category

Treatment - Drugs

4

Description

Control group: we will inject 5 milliliter normal saline plus 35 milliliter Rupivacaine 0/2%(Molteni Co.Italia)

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

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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

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

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alikalaliir@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 Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Dr Esmaeel Moshiri

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Latest degree

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Other areas of specialty/work

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Web page address

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 Moshiri

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

They have to write letters to the professors and the university

Comments

Person responsible for updating data

Contact