

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparing the effect of adding rocuronium and nitroglycerin to ropivacaine in reducing pain and hemodynamic changes in intravenous local anesthesia

Protocol summary

Study aim

Comparing the effect of adding rocuronium and nitroglycerin to ropivacaine in reducing pain and hemodynamic changes in intravenous local anesthesia

Design

The study will be double blind and clinical trial. 177 patients will be randomly divided into 3 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Candidate patients for forearm surgery in Valiasr hospital in Arak city are divided into 3 groups by randomization using the block method. The study is double-blind and blinding of the analyst and the outcome evaluator and the participant is done. Interventional drugs will be prescribed by an anesthesiologist, but the Bear Block technique and checking the effects and recording data will be done by a specialist assistant who is not aware of the groupings.

Participants/Inclusion and exclusion criteria

Inclusion criteria: candidate for forearm surgery, not suffering from Raynaud's disease, not suffering from sickle cell anemia, no cyanosis of the affected limb, no use of narcotics and psychoactive substances, no contraindications for intravenous anesthesia, no more than one fracture in the body or surgery. Exclusion criteria: the duration of the surgery is more than 90 minutes, for any reason, the local intravenous anesthesia is terminated (ineffective) during the operation, the duration of the operation is less than 30 minutes.

Intervention groups

The nitroglycerin group will be injected with 200 micrograms of nitroglycerin (Iran Caspin Company) along with 0.2% ropivacaine. The rocuronium group will be injected with 0.06 mg/kg of rocuronium along with 0.2% ropivacaine.

Main outcome variables

Sensory and motor block onset time, average heart rate,

average arterial blood pressure, pain, average drug consumption in 24 hours.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N183**

Registration date: **2023-05-23, 1402/03/02**

Registration timing: **prospective**

Last update: **2023-05-23, 1402/03/02**

Update count: **0**

Registration date

2023-05-23, 1402/03/02

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

2023-06-05, 1402/03/15

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of adding rocuronium and nitroglycerin to ropivacaine in reducing pain and hemodynamic changes in intravenous local anesthesia

Public title

The effect of rocuronium and nitroglycerin in reducing pain in intravenous local anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

20-65 years ASA class I and II Forearm surgery candidate
Consent to enter the study Not having Raynaud's disease
Not having sickle cell anemia No history of allergy to the drugs used in the study
Absence of cyanosis of the affected organ No use of drugs and psychotropic substances
No contraindications for intravenous anesthesia The absence of more than one fracture in the body or surgery
Absence of chronic pain syndrome
Absence of neurological disorders in the hand

Exclusion criteria:

The duration of surgery is more than 90 minutes For any reason, the local intravenous anesthesia is terminated (ineffective) during the operation. The duration of the operation is less than 30 minutes

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **177**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4. 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

Interventional drugs will be prescribed by an anesthesiologist, but the Bear Block technique and checking the effects and recording data will be done by a specialist assistant who is not aware of the groupings. In this way, due to the lack of knowledge of the patient and

the results evaluator about the order of the groups and interventions, the study will be double-blind.

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

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

City

Arak

Province

Markazi

Postal code

848176941

Approval date

2023-05-01, 1402/02/11

Ethics committee reference number

IR.ARAKMU.REC.1402.033

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

Forearm fracture

ICD-10 code

M21.83

ICD-10 code description

Other specified acquired deformities of forearm

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

Pain

Timepoint

After filling the tourniquet, and at times 15, 30 and 45 and every 15 minutes until the end of the surgery, after emptying the tourniquet every 30 minutes up to 2 hours (minutes 30, 60, 90 and 120) and then every two hours until 12 hours (4, 6, 8, 10 and 12 hours) after emptying the tourniquet

Method of measurement

Visual analog scale of pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The nitroglycerin group will be injected with 200 micrograms of nitroglycerin (Iran Caspin Company) along with 0.2% ropivacaine. The volume of ropivacaine in all groups will be 35 ml (70 mg) and the desired dose of adjuvant drug will be increased to 5 ml with distilled water, and finally the total volume of drug injected in IVRA in each patient will be 40 ml from the venous cannula site in all groups.

Category

Treatment - Drugs

2

Description

Intervention group: The rocuronium(behsan daru) group will be injected with 0.06 mg/kg of rocuronium along with 0.2% ropivacaine. The volume of ropivacaine in all groups will be 35 ml (70 mg) and the intended dose of adjuvant drug will be increased to 5 ml with distilled water, and finally the total volume of drug injected in IVRA in each patient is 40 ml from the venous cannula site in all groups.

Category

Treatment - Drugs

3

Description

Control group: As an adjuvant, 5 ml of normal saline with 35 ml of 0.2% ropivacaine with a total volume of 40 ml will be injected through the venous cannula.

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 square

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Email

modir.he@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University Of Medical Sciences

Full name of responsible person

Dr Mehdi Salehi

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

salehi@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, 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

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 scientific 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
Street address
Valiasr Hospital, Valiasr square, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
modir.he@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person

Dr Shiva Alikhani
Position
resident of anesthesiology
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Medicine department, Payambar Azam complex, Basij square, Sardasht, Arak, Iran
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
alikhani@gmail.com
Web page address

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