

# 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