

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Comparison of the success rate of axillary network block with 0.25% bupivacaine injection with or without dexamethasone, under ultrasound guide in upper limb trauma surgeries

#### Protocol summary

##### Study aim

Comparison of the success rate of axillary network block with 0.25% bupivacaine injection with or without dexamethasone under ultrasound guide in upper limb trauma surgery

##### Design

A double-blinded, randomized clinical trial with parallel groups design of 72 patients

##### Settings and conduct

This study is a clinical trial in Poursina Hospital in Rasht. Patients who are candidates for elective forearm surgery will be in one of the two groups, using the randomized blocks method. All nerve blocks (brachial axillary network) will be performed by the anesthesiologist in charge, using the M7 model ultrasound device with a 10 megahertz transformer (linear probe). The patient will be in the supine position while the shoulder is abducted and the elbow in the same hand is flexed. Using the nerve block needle No. 22, with a length of 5 centimeters, Arrow model, and in-plane technique, we enter from the lateral to the medial. Then the drugs will be injected into the nerve of the musculoskeletal, median, radial, and ulnar nerves. This study is double-blinded, patients and the evaluator and surgeon are blind and the anesthesiologist in charge is aware of the treatment groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with upper limb trauma, candidates for elective upper limb surgery, Age over 18 years, ASA class I-III Exclusion criteria: Diabetes, Drug addiction, Sepsis, Infection of the injection site, Sensitivity to local anesthetics, Coagulation disorder, Kidney or liver failure.

##### Intervention groups

Intervention group: Axillary network block with 30 milliliters of 0.25% bupivacaine plus 2 milliliters of dexamethasone (8 milligrams) Control group: Axillary

network block with 30 milliliters of bupivacaine 0.25% in addition to 2 milliliters of Sterile water

##### Main outcome variables

The intensity of sensory and motor blocks

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20121216011766N7**

Registration date: **2021-06-21, 1400/03/31**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-06-21, 1400/03/31**

Update count: **0**

##### Registration date

2021-06-21, 1400/03/31

##### Registrant information

##### Name

Hossein Khoshrang

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3355 0028

##### Email address

khoshrang@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-05, 1400/02/15

##### Expected recruitment end date

2022-05-05, 1401/02/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the success rate of axillary network block with 0.25% bupivacaine injection with or without dexamethasone, under ultrasound guide in upper limb trauma surgeries

**Public title**

Axillary network block under ultrasound guide in upper limb trauma surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with upper limb trauma, candidates for elective upper limb surgery Age over 18 years ASA class I-III

**Exclusion criteria:**

Diabetes Drug addiction Sepsis Infection of injection site Sensitivity to local anesthetics Coagulation disorder Kidney or liver failure History of previous weakness and paresis in the operation area History of axillary surgery

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All eligible individuals will be divided into intervention and control groups using block randomization method with 4 and 6 block sizes. To generate a randomization list from the online randomization service Sealed Envelope Ltd. 2019 was used (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants and the researcher collecting information will not be informed about the type of therapy received for each group in a double-blind manner, and each of the two types of treatment will be sent to therapists in a sealed envelope.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Guilan University of Medical Sciences

**Street address**

Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street, Rasht

**City**

Rasht

**Province**

Guilan

**Postal code**

4144654839

**Approval date**

2021-03-10, 1399/12/20

**Ethics committee reference number**

IR.GUMS.REC.1399.650

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

Control of acute pain after upper limb surgery

**ICD-10 code**

G89.11

**ICD-10 code description**

Acute pain due to trauma

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

Intensity of sensory block

**Timepoint**

After the anesthesia procedure, every 5 minutes along 30 minutes

**Method of measurement**

According to the Pinprick test: zero has a perfect sense, one a slight sense, two have no sense at all

**2****Description**

Intensity of motor block

**Timepoint**

After the anesthesia procedure, every 5 minutes along 30 minutes

**Method of measurement**

According to the Modified Bromage Scale: zero inability to move fingers, one only being able to move fingers, two being able to move and bend the wrist, three full elbow flexions.

## Secondary outcomes

### 1

#### Description

Possible side effects of injecting medication

#### Timepoint

During the procedure till the end of the surgery

#### Method of measurement

Checking of paraesthesia, incorrect intravascular injection, hematoma and nerve damage

## Intervention groups

### 1

#### Description

Intervention group: group of Bupivacaine injection 0.25% with dexamethasone: All nerve blocks (brachial axillary network) will be performed by the anesthesiologist in charge, using the M7 model ultrasound device with a 10 megahertz transformer (linear probe). Oxygen will be prescribed for all patients 6 Litre per minute with the mask. standard monitoring (pulse oximetry, ECG, and Blood pressure) will be performed. The patient will be in the supine position while the shoulder is abducted and the elbow in the same hand is flexed. With sterility, under direct ultrasound vision, while the linear probe is located as a short axis in the axillary region, the musculocutaneous nerve and the axillary artery will be seen. Then, using the nerve block needle No. 22, with a length of 5 centimeters, Arrow model, and in-plane technique, we enter from the lateral to the medial. First, 30 milliliters of 0.25% bupivacaine plus 2 milliliters of dexamethasone (8 milligrams) will be injected into the nerve of the musculoskeletal nerve and then into the median, radial, and ulnar nerves. After ensuring the patients' analgesia, the orthopedist will be allowed to perform the surgery. Midazolam 0.02 milligrams per kilogram is prescribed to all patients for sedation before the blockade. Fentanyl 0.5 macrogramms per kilograms is also given to prevent tourniquet pain.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Injection group of bupivacaine 0.25% without dexamethasone: All nerve blocks (brachial axillary network) will be performed by the anesthesiologist in charge, using the M7 model ultrasound device with a 10 megahertz transformer (linear probe). Oxygen will be prescribed for all patients 6 Litre per minute with the mask. standard monitoring (pulse oximetry, ECG, and Blood pressure) will be performed. The patient will be in the supine position while the shoulder is abducted and the elbow in the same hand is flexed. With sterility, under direct ultrasound vision, while the linear probe is located as a short axis in the axillary region, the musculocutaneous nerve and the axillary artery will be seen. Then, using

the nerve block needle No. 22, with a length of 5 centimeters, Arrow model, and in-plane technique, we enter from the lateral to the medial. First, 30 milliliters of 0.25% bupivacaine plus 2 milliliters of Sterile water will be injected into the nerve of the musculoskeletal nerve and then into the median, radial, and ulnar nerves. After ensuring the patients' analgesia, the orthopedist will be allowed to perform the surgery. Midazolam 0.02 milligrams per kilogram is prescribed to all patients for sedation before the blockade. Fentanyl 0.5 macrogramms per kilograms is also given to prevent tourniquet pain.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Poursina Hospital

##### Full name of responsible person

Dr Hossein Khooshrang

##### Street address

Poursina Hospital, Poursina Xrd, Hafez St, Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

4193713194

##### Phone

+98 13 3332 2444

##### Email

poursina@gums.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Guilan University of Medical Sciences

##### Full name of responsible person

Dr Mohammadreza Naghipoor

##### Street address

Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street, Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

6694941446

##### Phone

+98 13 3333 5821

##### Email

naghi@gums.ac.ir

##### Grant name

**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Vice President of Research Guilan 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**  
Anesthesiology Research Center  
**Full name of responsible person**  
Hossein Khoshrang  
**Position**  
Anesthesiologist  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Razi Hospital  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
4139638459  
**Phone**  
+98 13 3336 8534  
**Fax**  
+98 13 3336 8651  
**Email**  
arcguilan1392@gmail.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Anesthesiology Research Center  
**Full name of responsible person**  
Hossein Khoshrang  
**Position**  
Anesthesiologist  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology

**Street address**  
Razi Hospital  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
4139638459  
**Phone**  
+98 13 3336 8534  
**Fax**  
+98 13 3336 8651  
**Email**  
arcguilan1392@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Mohadese Ahmadi  
**Position**  
Senior Expert of Research Affairs/MSc in Teaching English as a foreign language  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Senior Expert of Research Affairs  
**Street address**  
Anesthesiology Research Center, Alzahra Hospital, Namjoo Street  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
4144654839  
**Phone**  
+98 13 3336 9328  
**Email**  
p.ahmadi2311@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