

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Comparison of ultrasound guided axillary brachial plexus block techniques: Perineural injection of brachial plexus versus single or double perivascular infiltration

#### Protocol summary

##### Study aim

Comparison of methods of axillary blockage of brachial plexus with ultrasound guidance

##### Design

Community based and pragmatic clinical trial with parallel groups

##### Settings and conduct

Injection of lidocaine 1% solution in the operating room of Shahid Beheshti Hospital in Babol by anesthesiologist and evaluation of the procedure time, block time and induction of anesthesia every 3 minutes up to 15 minutes after the block

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing upper limb surgery  
Conditions of non compliance: pregnant patients, coagulation disorders, localized infection, history of local anesthetic hypersensitivity

##### Intervention groups

Intervention group 1: single injection of Lidocaine 1% with epinephrine 1: 200,000 plus bicarbonate along the radial, median and ulnar nerves with ultrasonography guidance. Intervention group 2: single injection of Lidocaine 1% with epinephrine 1: 200,000 plus bicarbonate at 12 o'clock around the axillary artery with ultrasonography guidance. Intervention group 3: dual injection of Lidocaine 1% with epinephrine 1: 200,000 plus bicarbonate at 6 and 12 O'clock around the axillary artery with ultrasonography guidance.

##### Main outcome variables

The duration of the block (from the needle is inserted into the skin until the needle is removed from the skin); The degree of the sensory and motor block; Onset time (from the needle is removed to the complete block and allowing for the start of surgery); Induction time (from needle insertion to complete sensory and motor block)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160926029976N4**

Registration date: **2019-02-19, 1397/11/30**

Registration timing: **retrospective**

Last update: **2019-02-19, 1397/11/30**

Update count: **0**

##### Registration date

2019-02-19, 1397/11/30

##### Registrant information

##### Name

Reza Mohseni Ahangar

##### Name of organization / entity

Babol University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3223 8301

##### Email address

r.mohseni@mubabol.ac.ir

##### 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

2018-01-21, 1396/11/01

##### Actual recruitment end date

2019-01-21, 1397/11/01

##### Trial completion date

2019-01-21, 1397/11/01

### Scientific title

Comparison of ultrasound guided axillary brachial plexus block techniques: Perineural injection of brachial plexus versus single or double perivascular infiltration

### Public title

Brachial plexus block in Axilla with ultrasound guidance

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Candidate for upper limb surgery lower than elbow

#### Exclusion criteria:

pregnancy Coagulation disorders Infection in the site of the blockage History of local anesthetic hypersensitivity

### Age

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

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

Actual sample size reached: **60**

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

##### Street address

Babol university of medical science, Parastar Square, Keshavarz Blvd, Babol

##### City

Babol

##### Province

Mazandaran

##### Postal code

4717995915

#### Approval date

2019-01-01, 1397/10/11

### Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.215

## Health conditions studied

### 1

#### Description of health condition studied

Acquired deformity of musculoskeletal system, unspecified

#### ICD-10 code

M95.9

#### ICD-10 code description

Acquired deformity of musculoskeletal system, unspecified

## Primary outcomes

### 1

#### Description

Duration of the blockage

#### Timepoint

3 minutes after the intervention

#### Method of measurement

clock

### 2

#### Description

Degree of sensory and motor block

#### Timepoint

3 minutes after the intervention

#### Method of measurement

pinprick test

### 3

#### Description

Onset time of block

#### Timepoint

3 minutes after the intervention

#### Method of measurement

clock

### 4

#### Description

Induction time

#### Timepoint

3 minutes after the intervention

#### Method of measurement

clock

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group 1: Injection of solution of Lidocaine 1% with epinephrine 1:200,000 plus bicarbonate around the radial, ulnar and median nerve under the direction of ultrasound

### Category

Treatment - Drugs

## 2

### Description

Intervention group 2: Injection of solution of Lidocaine 1% with epinephrine 1:200,000 plus bicarbonate around the axillary artery at 12 o'clock under the direction of ultrasound

### Category

Treatment - Drugs

## 3

### Description

Intervention group 3: Injection of solution of Lidocaine 1% with epinephrine 1:200,000 plus bicarbonate on both sides of the axillary artery at 6 and 12 o'clock under the direction of ultrasound

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shahid Beheshti hospital

#### Full name of responsible person

Mostafa Molaie

#### Street address

Rohani hospital, Keshavarz boulevard

#### City

Babol

#### Province

Mazandaran

#### Postal code

47176-47745

#### Phone

+98 11 3223 8309

#### Email

r.mohseni@mubabol.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Reza Ghadimi

#### Street address

Babol University Of Medical Sciences, Ganjafrooz

Street, Babol

#### City

Babol

#### Province

Mazandaran

#### Postal code

4717995915

#### Phone

+98 11 3219 9592

#### Email

rezaghadimi@yahoo.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Babol 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

Babol University of Medical Sciences

#### Full name of responsible person

Mostafa Molaie

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Anesthesiology

#### Street address

Rohani hospital, Keshavarz Blvd

#### City

Babol

#### Province

Mazandaran

#### Postal code

4717647745

#### Phone

+98 11 3223 8309

#### Email

dr.mola.ghara@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Babol University of Medical Sciences

**Full name of responsible person**

Mostafa Molaie

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**Email**

dr.mola.ghara@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**

Not applicable

**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

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

Babol University of Medical Sciences

**Full name of responsible person**

Mostafa molaie

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology