

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The comparison of the effect of intravenous regional anesthesia (IVRA) with single-cuff forearm and upper arm tourniquets on the pain of patients undergoing elective hand surgery

Protocol summary

Study aim

The comparison of the effect of intravenous regional anesthesia (IVRA) with single-cuff forearm and upper arm tourniquets on the pain of patients undergoing elective hand surgery

Design

A randomized clinical trial with parallel groups. 60 patients have randomly divided into intervention groups A and B with a table of random numbers and Randomizer software.

Settings and conduct

The population of this study was aged 20-60 years old who referred to Ayatollah Rouhani Hospital in Babol. Patients are randomly divided into two Intervention groups with a Table of random numbers by computer. Intervention group A: use of a single tourniquet in the forearm (distal) + lidocaine intravenous injection of 100 mg Intervention group B: use of a single tourniquet in the upper arm (proximal) + lidocaine intravenous injection of 200 mg.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 20--60 years old, Patients undergoing hand surgeries ASA Class I, II Exclusion Criteria: Psychologic, patients Addiction, History of allergy to local anesthetics, Epilepsy History of peripheral vascular disease, Coagulopathy, Pregnancy, Open wound in operation

Intervention groups

Intervention group A: use of a single tourniquet in the forearm (distal) + lidocaine intravenous injection of 100 mg Intervention group B: use of a single tourniquet in the upper arm (proximal) + lidocaine intravenous injection of 200 mg.

Main outcome variables

Anesthesia quality, the onset of local anesthetic effect, change in anesthetic method, duration of analgesia, pain intensity of the area, the duration of pain in the area of

operation, pain intensity of the tourniquet (arm/forearm)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101213005381N13**

Registration date: **2019-01-26, 1397/11/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-26, 1397/11/06**

Update count: **0**

Registration date

2019-01-26, 1397/11/06

Registrant information

Name

Nadia Banihashem

Name of organization / entity

Babol University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 22 38296

Email address

nbanihashem@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The comparison of the effect of intravenous regional anesthesia (IVRA) with single-cuff forearm and upper arm tourniquets on the pain of patients undergoing elective hand surgery

Public title
Effect of intravenous regional anesthesia in Hand surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 20--60 years old Patients undergoing hand surgeries ASA Class I, II
Exclusion criteria:
 Psychologic patients Addiction History of allergy to local anesthetics Epilepsy History of peripheral vascular disease Coagulopathy Pregnancy Open wound in operation site

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients into two intervention groups Patients are randomly divided into two groups A and B with a table of random numbers (a random number table is a collection of numbers that are generated without a specific pattern or order and completely randomized, then samples are randomly selected by Randomizer software.

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

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Approval date

2018-12-16, 1397/09/25

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.208

Health conditions studied

1

Description of health condition studied

injury of wrist, hand and fingers

ICD-10 code

S60

ICD-10 code description

Superficial injury of wrist, hand and fingers

Primary outcomes

1

Description

Analgesia

Timepoint

1, 5, 10, 20, 30 mints after tornique inflation & 1, 5, 10 mints & 2 hours after unfastening the tornique

Method of measurement

Visual Analogue Scale - Visual -questionnaire

Secondary outcomes

1

Description

Time to the beginning of tourniquet pain

Timepoint

Once when the patient complained

Method of measurement

Time elapsed from tourniquet inflation in minutes

2

Description

Time to the first request for analgesic

Timepoint

Once at the moment of first request

Method of measurement

Time elapsed from tourniquet deflation in minutes

Intervention groups

1

Description

Intervention group A: Use of a single tourniquet in the forearm (distal) + lidocaine intravenous injection of 100 mg

Category

Treatment - Other

2

Description

Intervention group B: Use of a single tourniquet in the upper arm (proximal) + lidocaine intravenous injection of 200 mg

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Nadia Banihashem

Street address

Ruhani Hospital, Daneshgah Square, Ganjafrroz Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Reza Ghadimi

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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

Nadia Banihashem

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Latest degree

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Person responsible for updating data

Contact

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Full name of responsible person

Massomeh Mousavi

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Latest degree

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Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is still no plan for its publish

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available