Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ClassI, 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

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Iran (Islamic Republic of)

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+98 22 38296

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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 ClassI,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
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Ruhani Hospital, Daneshgah Square, Ganjafrooz 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
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Nadia Banihashem
Position
Assistant professor
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Person responsible for updating data

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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 puplish
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