

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

A comparison between intravenous regional anesthesia and spinal block efficacy in foot surgery

Protocol summary

Study aim

A comparison between intravenous regional anesthesia and spinal block efficacy in the foot 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 15-70 years old who referred to Ayatollah Rouhani Hospital in Babol. Patients are randomly divided into two Intervention groups (A and B) with a Table of random numbers by computer. All patients would receive the same premedication (200 ml of normal saline, 1 mg of midazolam and 50 micrograms fentanyl). Intervention group A: The Intravenous regional anesthesia with 200 mg lidocaine diluted with normal saline (40 ml) and Intervention group B: The spinal anesthesia in the sitting position with Marcaine 0.5% at 12 mg

Participants/Inclusion and exclusion criteria

Inclusion criteria: 15 to 70-year-old patients ASA class 1,2 Exclusion criteria: Emergency patients, vascular dysfunction and chronic diabetes

Intervention groups

Intervention group A: The intravenous regional anesthesia with 200 mg lidocaine diluted with normal saline (40 ml). Intervention group B: The spinal anesthesia in the sitting position with Marcaine 0.5% at 12 mg

Main outcome variables

Anesthesia quality, the onset of local anesthetic effect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101013004923N8**

Registration date: **2019-02-22, 1397/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-22, 1397/12/03**

Update count: **0**

Registration date

2019-02-22, 1397/12/03

Registrant information

Name

Bahman Hasannasab

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 8296

Email address

bahmanh2002@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between intravenous regional anesthesia and spinal block efficacy in foot surgery

Public title

Intravenous regional anesthesia and spinal block efficacy

in foot surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
15 to 70-year-old patients ASA class 1,2
Exclusion criteria:
Emergency patients Vascular dysfunction Chronic diabetes

Age
From **15 years** old to **70 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
Patients are randomly divided into two intervention A and B groups 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.1397.239

Health conditions studied

1

Description of health condition studied
Local anaesthetics
ICD-10 code
Y48.3
ICD-10 code description
Local anaesthetics

Primary outcomes

1

Description
Onset of analgesia
Timepoint
Every 5 minutes after start of anesthetics injection
Method of measurement
Evaluate the patients response to needle hitting on surgical site

Secondary outcomes

1

Description
Postoperative Pain
Timepoint
1, 6, 12, 24 Hours after operation
Method of measurement
Visual Analog Scale

2

Description
Overall analgesic requirement post operative
Timepoint
In the first 24 hours after operation
Method of measurement
Nursing Report

Intervention groups

1

Description
Intervention group: All patients would receive the same premedication (200 ml of normal saline, 1 mg of midazolam and 50 micrograms fentanyl). intravenous regional anesthesia with 200 mg lidocaine diluted with normal saline (40 ml) would be done.
Category
Treatment - Drugs

2

Description
Intervention group: All patients would receive the same premedication (200 ml of normal saline, 1 mg of midazolam and 50 micrograms fentanyl). The spinal

anesthesia in the sitting position with Marcaine 0.5% at 12 mg would be done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Bahman Hassannasab

Street address

Ruhani Hospital, Daneshgah Square, Ganjafrroz Avenue

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+98 11 3223 8301

Email

bahmanh2002@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

Vice-chancellor Of Research, Daneshgah Square, Ganjafrroz Avenue

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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

Bahman Hassannasab

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrroz Avenue

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Bahman Hassannasab

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Noreddin Taghavi

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Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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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