

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The analgesic effect of paracetamol when added to lidocaine for intravenous regional anesthesia

Protocol summary

Study aim

The analgesic effect of paracetamol when added to lidocaine for intravenous regional anesthesia

Design

A randomized clinical trial with parallel groups. 60 patients have randomly divided into intervention groups A, B and C 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 three Intervention groups with a Table of random numbers by computer.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 20--60 years old, Patients undergoing hand surgeries, ASA Class I, II Exclusion Criteria: History of allergic reaction, Addiction, Pregnancy

Intervention groups

Intervention group A: intravenous regional anesthesia with 200 mg lidocaine diluted with normal saline (40 ml) would be done. Also, patients received with peripheral venous catheter 20 ml normal saline. Intervention group B: All patients would received the same premeditation (200 ml of normal saline, 1 mg of midazolam and 50 micrograms fentanyl). intravenous regional anesthesia with 300 mg parasetamol (40 ml) would be done. Also, patients received with peripheral venous catheter 20 ml normal saline. Intervention group C: All patients would received the same premeditation (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. Also, patients received with peripheral venous catheter 300 mg of paracetamol (20 ml).

Main outcome variables

Surgical site pain, Onset and duration of sensory and motor block, Time to the first request for analgesic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141121020020N3**

Registration date: **2019-08-18, 1398/05/27**

Registration timing: **retrospective**

Last update: **2019-08-18, 1398/05/27**

Update count: **0**

Registration date

2019-08-18, 1398/05/27

Registrant information

Name

Shahram Seyfi

Name of organization / entity

Babol University of Medical Science

Country

Iran (Islamic Republic of)

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Email address

sh.seyfi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

2013-07-23, 1392/05/01

Actual recruitment end date

2014-01-21, 1392/11/01

Trial completion date

2014-01-21, 1392/11/01

Scientific title

The analgesic effect of paracetamol when added to lidocaine for intravenous regional anesthesia

Public title

The analgesic effect of paracetamol when added to lidocaine for intravenous regional anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

20--60 years old Patients undergoing hand surgeries ASA Class I, II

Exclusion criteria:

History of allergic reaction Addiction Pregnancy

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**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into three groups A, B and C 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, The participants allocation sequence in three groups performed with a 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

2013-07-16, 1392/04/25

Ethics committee reference number

MUBABOL.REC.1392.21

Health conditions studied

1

Description of health condition studied

Intera venous Regional Anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

Surgical site pain

Timepoint

After the start of surgical process (at 5, 10, 15, 20, 30, 40 and 50 min) and after the end of surgery

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Onset and duration of sensory and motor block

Timepoint

From the start of anesthetics injection to the end of operation

Method of measurement

Evaluate the patients response to needle hitting on surgical site and request of the patients to hand flexion and extension

3

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

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients would received 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. Also, patients received with peripheral venous catheter 20 ml normal saline.

Category

Treatment - Drugs

2

Description

Intervention group: All patients would received the same premedication (200 ml of normal saline, 1 mg of midazolam and 50 micrograms fentanyl).intravenous regional anesthesia with 300 mg parasetamol (40 ml) would be done.Also, patients received with peripheral venous catheter 20 ml normal saline.

Category

Treatment - Drugs

3

Description

Intervention group: All patients would received 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. Also, patients received with peripheral venous catheter 300 mg of paracetamol (20 ml).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

shahram Seyfi

Street address

Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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+98 11 3233 8301

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ficu_ss@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Reza Ghadimi

Street address

Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

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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

Shahram Seyfi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Latest degree

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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 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