

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison between magnesium sulfate and paracetamol in Analgesic effect and venous blood gas alterations during Intravenous Regional Anesthesia with Lidocaine

Protocol summary

Summary

This study will be performed by the aim of comparison the analgesia and venous blood gas alterations by adding Paracetamol or Magnesium Sulphate to Lidocaine in upper extremity surgeries under intravenous regional anesthesia as a double blinded clinical trial with placebo. Ninety ASA class I, II patients between 15 to 65 years divided into 3 groups of 30 cases. Allergic reaction to Lidocaine, Acetaminophen or Magnesium sulphate is the main exclusion criterion. Group 1(control) will receive 3 mg/kg Lidocaine 0.5% plus Saline IV by the volume of 40 ml. Group 2(Magnesium Sulphate) will get 3 mg/kg Lidocaine 0.5% plus 10 ml Magnesium Sulphate 15% and Saline IV by the volume of 40 ml. Group 3(Paracetamol) will have 3 mg/kg Lidocaine 0.5% plus 300 mg Paracetamol and Saline IV by the volume of 40 ml. Sensory block evaluation will be done by pinprick and motor block by inability to move the extremity which will be assessed every 30 seconds. Visual Analog scale is used for measure pain sensation. If tourniquet pain produces VAS =4 or more, 1 mic/kg Fentanyl will be injected. Venous PH, PO2 and PCO2 at the beginning and before deflation of tourniquet will be measured. At the first time after operation by VAS=4, 2 mg of Morphine IV will be given every 15 minutes to decrease the score to 3 or less. Total dose of Morphine and VAS, BP, HR and SPO2 will be assessed during 24 hour

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112254046N2**
Registration date: **2012-01-08, 1390/10/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-08, 1390/10/18

Registrant information

Name

Alireza Mirkheshti

Name of organization / entity

Shahid Beheshti university of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-12-03, 1390/09/12

Expected recruitment end date

2012-03-18, 1390/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between magnesium sulfate and paracetamol in Analgesic effect and venous blood gas alterations during Intravenous Regional Anesthesia with Lidocaine

Public title

Comparison between Magnesium sulphate and

Paracetamol in intravenous regional anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1. Age between 15 to 65 years 2. Appropriate general condition as American Society of Anesthesiologist (ASA) class I and II 3. Upper extremity surgeries 4. Operation time less than 2 hours Exclusion criteria: 1. Any allergic reaction to Lidocaine, Acetaminophen or Magnesium Sulphate 2. Any cyanosis in affected limb 3. Any opioid or psychoactive drug abuse

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University of Medical Sciences

Street address
Velenjak street

City
Tehran

Postal code
1985717443

Approval date
2011-02-27, 1389/12/08

Ethics committee reference number
89-01-148-7489-1

Health conditions studied

1

Description of health condition studied
local anesthetics

ICD-10 code

Y48.3

ICD-10 code description

Anesthesia-regional

Primary outcomes

1

Description
Sensory block

Timepoint
During and after operation

Method of measurement
Pinprick test

2

Description
Motor block

Timepoint
During and after operation

Method of measurement
Remove of all hand movements

3

Description
Venous blood gas

Timepoint
Before and after procedure

Method of measurement
Venous blood sample

4

Description
Pain

Timepoint
During the operation and 24 hours after that

Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Saturation of oxygen

Timepoint
Durig operation and 24 hours after that

Method of measurement
Pulse oximetry

2

Description
Blood pressure

Timepoint
During operation and 24 hours after that

Method of measurement
Blood pressure manometer

3

Description

Heart rate

Timepoint

During operation and 24 hours after that

Method of measurement

Pulse oximetry

Intervention groups

1

Description

Control group:they will receive Lidocaine 0.5% , 3 mg/kg plus normal saline intravenously by the total volume of 40 ml .

Category

Treatment - Drugs

2

Description

Magnesium Sulphate (intervention) group:they will receive Lidocaine 0.5%, 3 mg/kg plus magnesium sulphate 15%, 10 ml (Magnesium Sulphate 20% Hypertonic, made by Pastor Institute-iran)and normal saline intravenously by the total volume of 40 ml.

Category

Treatment - Drugs

3

Description

Paracetamol(intervention) group:they will receive Lidocaine 0.5%, 3 mg/kg plus Paracetamol (Apotel,made by Unipharma, Greece) 1000 mg and normal saline intravenously by the total volume of 40 ml.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Alireza Mirkheshti MD

Street address

Shahid Madani street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Anesthesiology research center,Shahid Beheshti

University of Medical Sciences

Full name of responsible person

Taheri

Street address

Ayatollah Taleghani Hospital- Velenjak Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Anesthesiology research center,Shahid Beheshti
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Anesthesiology research center-Shahid Beheshti
University ,M.C

Full name of responsible person

Mrs.Taheri

Position

Official clerk

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Imam Hossein Hospital

Full name of responsible person

Alireza Mirkheshti MD

Position

Assistant professor of Anesthesiology

Other areas of specialty/work

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Name of organization / entity
Imam Hossein Hospital
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Position
Assistant professor of anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty