Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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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

Ŝhahid 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 oximetery

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 oximetery

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 Institude-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
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Person responsible for scientific inquiries

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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