Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of analgesia due to nitroglycerine & meperidine added to lidocaine to lidocaine and meperidine in the IV regional anesthesia

Protocol summary

Summary

The purpose of this clinical trial is to compare analgesia due to nitroglycerin and meperidine added to lidocaine to lidocaine and meperidine in the IV regional anesthesia. A total of 50 patients aged 18-60 years old who are candidates for hand and wrist surgery are randomly assigned into one of the intervention groups. After BP and HR measurement and sedating by 1microg/kg IV fentanyl and 1.5 mg Midazolam double cough tornique is fastened around the arm. Blood of the organ is discharged by smarch band and proximal cough is inflated.150mmHg more than systolic Blood Pressure then the smarch band is unfastened. 200mg lidocaine & 50 mg Meperidine (totally40cc) is infused during 90 seconds in the case group & 200mg lidocaine , 50mg meperidine & 200 microg Nitroglycerin is infused in the control group . After feeling pain, Proximal tornique is difelated and distal tornique is inflated. 150mmHg more than systolic BP. BP & HR & VAS (Visual analog scaling) (Painless 0-Very painful 10) is checked 1, 5,10,20,30 mins after tornique inflation & 1,5,10 mins & 2 hours after tornique defilation. During the surgery 1-3microg/kg fentanyl is injected if there was a pain & if the pain was not controlled General Anesthesia is considered. The patient is asked about the surgical pain and the pain caused by Tornique and the end of the surgery. The quality of painlessness is divided in 3 groups: excellent (Painless), Good (Little pain & no need to infuse fentanyl), intermediate (sever pain which relieves by fentanyl),Bad (Patient who doesn't tolerate IV Local Anesthesia). The period of time from operating the tornique until 2 hours after asking for an analgesic is considered as the onset of the pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012254923N2**

Registration date: **2011-11-07, 1390/08/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-11-07, 1390/08/16

Registrant information

Name

Bahman Hasannasab

Name of organization / entity

Babol University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor of Research, Babol University of Medical Sciences

Expected recruitment start date

2009-11-22, 1388/09/01

Expected recruitment end date

2010-11-22, 1389/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesia due to nitroglycerine & meperidine added to lidocaine to lidocaine and meperidine in the IV regional anesthesia

Public title
Comparison of analgesia due to nitroglycerine & meperidine added to lidocaine to lidocaine and meperidine in the IV regional anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age 18-60 year old, candidate for hand and wrist surgery Exclusion criteria: history of hypertension, Diabetes, Convulsion, Sensitivity to general anesthetics, Dependency on narcotics
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Babol University of Medical Sciences
Street address
Daneshgah Sq., Ganjafrooz St., Babol
City
Babol
Postal code
Approval date
2009-07-07, 1388/04/16
Ethics committee reference number
3861/30/پ/ژ

Health conditions studied

1

Description of health condition studied
Injuries to the wrist and hand
ICD-10 code
S60, S61,
ICD-10 code description
Superficial injury of wrist and hand

2

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

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
Blood Pressure
Timepoint
1, 5, 10, 20, 30 mints after tornique inflation & 1, 5, 10 mints & 2 hours after unfastening the tornique
Method of measurement
BP Cuff

2

Description
Heart Rate
Timepoint
1, 5, 10, 20, 30 mints after tornique inflation & 1, 5, 10 mints & 2 hours after unfastening the tornique
Method of measurement
Pulse Oximeter - ECG

Intervention groups

1

Description
Intervention group: 200mg Lidocaine, 50mg Meperidine & 200 microgram TNG (Totally 40 cc) is injected IV in Hand
Category
Treatment - Drugs

2

Description
Control group: 200mg Lidocaine, 50mg Meperidine

(Totally 40 cc) is injected IV in Hand

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr Bahman Hasannasab

Street address

Sargurd Ghasemi St -Babol

City

Babol

2

Recruitment center

Name of recruitment center

Shahid Yahyanejad Hospital

Full name of responsible person

Dr Bahman Hasannasab

Street address

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Bahman Hasannasab

Street address

Anesthesiology Department -Ayatollah Ruhani Hospital

City

Babol

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

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University Of Medical Sciences

Full name of responsible person

Dr Bahman Hasannasab

Position

Assistant Professor Of Anesthesiology

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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