

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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 tournique 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 tournique is difelated and distal tournique 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 tournique inflation & 1,5,10 mins & 2 hours after tournique 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 Tournique 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 tournique 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 1223 8296

###### Email address

bahmanh2002@mubabol.ac.ir

##### 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**

**Street address**

Anesthesiology Department -Ayatollah ruhani Hospital

**City**

Babol

**Postal code**

**Phone**

+98 111223896

**Fax**

**Email**

bahmanh2002@yahoo.com

**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*