

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

A comparison of analgesia, duration of surgery, clinician and patients satisfaction and complications of Bier block versus conscious sedation methods in patients with upper extremity trauma

Protocol summary

Summary

We aimed to compare Bier block and systemic analgesia regarding level of analgesia, complications, duration, hemodynamic stability and satisfaction of surgeon, physician and patient in this study. This is a non-blinded randomized clinical trial which includes all upper extremity trauma patients in need of analgesia which are referred to Imam Khomeini and Beesat hospital in Tehran, Iran during years 2012 and 2013. Sample selection was simple random sampling and then, patients were randomly allocated into two groups- Bier block and systemic analgesia. Age, sex, type and site of injury were determined in each group. We used numerical rating scale (NSR) for assessing level of analgesia and five benchmark value for assessing surgeon, physician and patient satisfaction. We recorded the time of initiation of analgesia and procedure, end of procedure, patient's consciousness and discharge and also recorded patient's vital signs at the time of initiation of analgesia, end of procedure and discharge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202289162N1**
Registration date: **2013-01-31, 1391/11/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-31, 1391/11/12

Registrant information

Name

Amir Nejati

Name of organization / entity

Tehran University of Medical Sciences, Imam Khomeini Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2240

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Recruitment status

Recruitment complete

Funding source

Iranian National foundation of elites

Expected recruitment start date

2012-12-30, 1391/10/10

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of analgesia, duration of surgery, clinician and patients satisfaction and complications of Bier block versus conscious sedation methods in patients with upper extremity trauma

Public title

A comparison between two analgesia method in patients with upper extremity injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with upper extremity trauma; in need of analgesia; time of admission during years

2012 and 2013; place of admission Imam Khomeini and Beesat hospital, Tehran, Iran exclusion criteria: history of seizure; known allergy to analgesic substances; peripheral vascular disease; sickle cell anemia; AV fistula in upper extremity; upper extremity infection; procedures that lasts more than one hour; patients who need emergent intervention

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 68

Randomization (investigator's opinion)

Randomized

Randomization description

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 AJA U niversity of Medical Sciences

Street address

Etemadzade St, Fatemi St,

City

Tehran

Postal code

Approval date

2012-11-21, 1391/09/01

Ethics committee reference number

9109

Health conditions studied

1

Description of health condition studied

Superficial injury of forearm

ICD-10 code

S50

ICD-10 code description

Superficial injury of forearm

2

Description of health condition studied

Open wound of forearm

ICD-10 code

S51

ICD-10 code description

Open wound of forearm

3

Description of health condition studied

Fracture of forearm

ICD-10 code

S52

ICD-10 code description

Fracture of forearm

4

Description of health condition studied

Dislocation, sprain and strain of joints and ligaments of elbow

ICD-10 code

S53

ICD-10 code description

Dislocation, sprain and strain of joints and ligaments of elbow

5

Description of health condition studied

Injury of blood vessels at forearm level

ICD-10 code

S55

ICD-10 code description

Injury of blood vessels at forearm level

6

Description of health condition studied

Injury of muscle and tendon at forearm level

ICD-10 code

S56

ICD-10 code description

Injury of muscle and tendon at forearm level

7

Description of health condition studied

Crushing injury of forearm

ICD-10 code

S57

ICD-10 code description

Crushing injury of forearm

8

Description of health condition studied

Other and unspecified injuries of forearm

ICD-10 code

S59

ICD-10 code description

Other and unspecified injuries of forearm

9

Description of health condition studied

Superficial injury of wrist and hand

ICD-10 code

S60

ICD-10 code description

Superficial injury of wrist and hand

10

Description of health condition studied

Open wound of wrist and hand

ICD-10 code

S61

ICD-10 code description

Open wound of wrist and hand

11

Description of health condition studied

Fracture at wrist and hand level

ICD-10 code

S62

ICD-10 code description

Fracture at wrist and hand level

12

Description of health condition studied

Dislocation, sprain and strain of joints and ligaments at wrist and hand level

ICD-10 code

S63

ICD-10 code description

Dislocation, sprain and strain of joints and ligaments at wrist and hand level

13

Description of health condition studied

Injury of blood vessels at wrist and hand level

ICD-10 code

S65

ICD-10 code description

Injury of blood vessels at wrist and hand level

14

Description of health condition studied

Injury of muscle and tendon at wrist and hand level

ICD-10 code

S66

ICD-10 code description

Injury of muscle and tendon at wrist and hand level

15

Description of health condition studied

Crushing injury of wrist and hand

ICD-10 code

S67

ICD-10 code description

Crushing injury of wrist and hand

16

Description of health condition studied

Other and unspecified injuries of wrist and hand

ICD-10 code

S69

ICD-10 code description

Other and unspecified injuries of wrist and hand

Primary outcomes

1

Description

level of analgesia

Timepoint

after performance of sedation method

Method of measurement

NSR (numerical scaling rate)

Secondary outcomes

1

Description

satisfaction

Timepoint

after performance of sedation method

Method of measurement

five benchmark value

2

Description

complications

Timepoint

after procedural sedation

Method of measurement

qualitative value

3

Description

hemodynamic changes (pulse rate, mean arterial pressure)

Timepoint

before and after procedural sedation, before initiation of procedure, at the end of procedure, at the time of discharge

Method of measurement

cardiac monitoring

Intervention groups

1

Description

systemic analgesia: midazolam with a dose of 0.04mg/kg and phentanyl with a dose of 2 micrograms/kg

Category

Treatment - Surgery

2

Description

Bier block: 30-50 of lidocaine solution with a dose of 0.5% is injected into local venous circulation during 7 minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Amir Nejati M.D.

Street address

Faculties office, Emergency Department, Imam Khomeini Hospital, Tohid Square

City

Tehran

2

Recruitment center

Name of recruitment center

Beesat hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

AJA University of Medical Sciences

Full name of responsible person

Dr.Dormanesh

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Department of Education, AJA University of Medical Sciences, Etemadzade St,Fatemi St.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

AJA 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

Iranian national foundation of ellites

Full name of responsible person

Mohammad Ali Nikoo

Position

MD

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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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