Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Email address

a-nejati@tums.ac.ir

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 exterimity 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 exterimity; upper exterimity 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 prosedure, 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
Amir Nejati M.D.
Street address
Faculties office, Emergency Department, Imam Khomeini Hosptai, Tohid square
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
AJA University of Medical Sciences
Full name of responsible person
Dr.Dormanesh
Street address
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
Street address
No.18, 19th Unit, Marzdaran St, Fereshtegan Lane,
City
Tehran
Postal code
Phone
002144242502
Fax
Email
mohammadalinikoo@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran Uiversity of Medical Science
Full name of responsible person
Amir Nejati
Position
Assistant Professor, Faculty of educational group of Emergency Medicine
Other areas of specialty/work
Street address
Bagherkhan street, Chamran highway, Tohid square
City
Teharn
Postal code
Phone
+98 21 6690 4848
Fax
Email
a-nejati@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Amir Nejati
Position

Assistant Professor, Faculty of educational group of Emergency Medicine

Other areas of specialty/work

Street address

Bagherkhan street, Chamran highway, Tohid square

City

Tehran

Postal code

Phone

+98 21 6690 4848

Fax

Email

a-nejati@tums.ac.ir

Web page address

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