Clinical Trial Protocol
Iranian Registry of Clinical Trials
20 Aug 2019

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 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 analgesics 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

Groups that have been masked

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 University 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
### Description of health condition studied

Superficial injury of wrist and hand

#### ICD-10 code

S61

#### ICD-10 code description

Open wound 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**
Amir Nejati M.D.

**Street address**
Faculties office, Emergency Department, Imam Khomeini Hospital, 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**

---

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**
Iranian national foundation of elites

**Full name of responsible person**
Mohammad Ali Nikoo

**Position**
MD

**Other areas of specialty/work**

**Street address**
No.18, 19th Unit, Marzdan 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 University 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**
Tehran

**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)