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

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
None
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
<table>
<thead>
<tr>
<th>Description of health condition studied</th>
<th>ICD-10 code</th>
<th>ICD-10 code description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial injury of wrist and hand</td>
<td>S61</td>
<td>Open wound of wrist and hand</td>
</tr>
<tr>
<td></td>
<td></td>
<td>S69</td>
</tr>
<tr>
<td>Other and unspecified injuries of wrist and hand</td>
<td></td>
<td>Other and unspecified injuries of wrist and hand</td>
</tr>
</tbody>
</table>

**Primary outcomes**

<table>
<thead>
<tr>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of analgesia</td>
<td>after performance of sedation method</td>
<td>NSR (numerical scaling rate)</td>
</tr>
</tbody>
</table>

**Secondary outcomes**

<table>
<thead>
<tr>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction</td>
<td>after performance of sedation method</td>
<td>five benchmark value</td>
</tr>
<tr>
<td>Complications</td>
<td>after procedural sedation</td>
<td>qualitative value</td>
</tr>
</tbody>
</table>

**Intervention groups**

<table>
<thead>
<tr>
<th>Description</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systemic analgesia: midazolam with a dose of 0.04mg/kg and phentanyl with a dose of 2 micrograms/kg</td>
<td>Treatment - Surgery</td>
</tr>
<tr>
<td>Bier block: 30-50 of lidocaine solution with a dose of 0.5% is injected into local venous circulation during 7 days</td>
<td></td>
</tr>
</tbody>
</table>
### Recruitment centers

1

<table>
<thead>
<tr>
<th>Recruitment center</th>
<th>Name of recruitment center</th>
<th>Full name of responsible person</th>
<th>Street address</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Imam Khomeini hospital</td>
<td>Amir Nejati M.D.</td>
<td>Faculties office, Emergency Department, Imam Khomeini Hospital, Tohid Square</td>
<td>Tehran</td>
</tr>
</tbody>
</table>

2

<table>
<thead>
<tr>
<th>Recruitment center</th>
<th>Name of recruitment center</th>
<th>Full name of responsible person</th>
<th>Street address</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Beesat hospital</td>
<td>Amir Nejati M.D.</td>
<td>Faculties office, Emergency Department, Imam Khomeini Hospital, Tohid Square</td>
<td>Tehran</td>
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</tbody>
</table>

### Sponsors / Funding sources

1

<table>
<thead>
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<th>Sponsor</th>
<th>Name of organization / entity</th>
<th>Full name of responsible person</th>
<th>Street address</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AJA University of Medical Sciences</td>
<td>Dr. Dormanesh</td>
<td>Department of Education, AJA University of Medical Sciences, Etemadzade St, Fatemi St.</td>
<td>Tehran</td>
</tr>
</tbody>
</table>

Type of organization providing the funding: empty

### 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, 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 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)