Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the combination of dexmedethomidine and fentanyl with midazolam and fentanyl in induction of sedation and analgesia for reduction of distal radial fracture in the emergency department

Protocol summary

Study aim

Determination of the efficacy of dexmedethomidine and fentanyl with midazolam and fentanyl in induction of sedation and analgesia to reduction of distal radial fracture in the emergency department

Design

This randomized clinical trial was conducted in emergency department of Shahid Beheshti University of Medical Sciences. The trial phase was 1 and 2. All patients who referred to the emergency department with a distal radial fracture and who were between the ages of 18 and 60 years were included in the study. The sample size was about 40 people. Patients were randomly assigned into 2 groups and their demographic information was recorded and for induction of sedation and analgesia the first group was given midazolam and fentayl and the second group received dexmedethomidine and fentanyl. And the outcomes were measured before, during and after the procedure and recorded in both groups.

Settings and conduct

Patients with a distal radial fracture who were referred to the emergency department of Imam Hossein and Haft e Tir Hospital were included. The study was conducted as a single-blind as it was not possible to double blinding because the difference in the method of administration of the drug. Clinical investigator and clinical observer were aware of the study but the Patient and outcome evaluator and statistical analyzer were unaware of the study.

Participants/Inclusion and exclusion criteria

All patients between the ages of 18 and 60 who referred to the emergency department with Radius distal fracture were included. Patients under the age of 18 and over the age of 60 years, patients with a history of antihypertensive or antihistaminic use, patients with severe accompanying injuries such as head trauma and GCS <15, severe chest trauma, Cervical spine trauma with unstable fracture, and patients with mental retardation, hemodynamically unstable patients , patients with history of heart disease (cardiac block and bradycardia), pregnant women, Opioids addiction and substance abuse, and history Sensitivity to any of the medications that should be used.

Intervention groups

Patients with distal radial fracture who referred to the emergency department from each two genders

Main outcome variables

The variables studied included: age, sex, severity of pain, blood pressure, heart rate, respiratory rate, arterial oxygen saturation, apnea, bradycardia, nausea and vomiting

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20160401027165N1**
Registration date: **2018-01-13, 1396/10/23**
Registration timing: **retrospective**

Last update: **2018-01-13, 1396/10/23**
Update count: **0**

Registration date

2018-01-13, 1396/10/23

Registrant information

Name

Ali Arhami

Name of organization / entity

Country

Iran (Islamic Republic of)

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aliarhami@sbmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2014-04-22, 1393/02/02
Expected recruitment end date
2015-04-21, 1394/02/01
Actual recruitment start date
2014-04-21, 1393/02/01
Actual recruitment end date
2016-04-20, 1395/02/01
Trial completion date
empty

Scientific title
Comparison of the combination of dexmedethomidine and fentanyl with midazolam and fentanyl in induction of sedation and analgesia for reduction of distal radial fracture in the emergency department

Public title
The role of dexmedethomidine in sedation and analgesia in the emergency department
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients aged 18 to 60 years old who referred to the emergency department with a distal radial fracture
Exclusion criteria:
patient who taking antihypertensive or antihistaminic drugs patient aged less than 18 years Severe associated injury include: Head trauma and deceased level of consciousness (GCS <15), Severe chest trauma Cervical spine trauma with unstable fracture Patients with hemodynamic instability Patients with mental retardation Patients with a history of heart disease (bradycardia and any AV heart block) pregnant patient history of allergy to midazolam, fentanyl and dexmedethomidine addiction to opioids and substance abuse
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the researcher and clinical caregiver (professor and assistant) were not blinded due to the difference in method of each drug administration and also the need for knowledge about the type of administrating drug to deal with their possible side effects and complication, But the outcome elevator (the second senior assistant) and the data analyzer were unaware of the study
Placebo
Not used
Assignment
Parallel
Other design features
does not have

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Scinces
Street address
Tabnak St, Yaman St, Shahid Chamran highway
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2017-10-06, 1396/07/14
Ethics committee reference number
Sbmu.rec.1392.440

Health conditions studied

1

Description of health condition studied
distal radial fracture
ICD-10 code
(S60-S68)
ICD-10 code description
Injury to the wrist and hand

Primary outcomes

1

Description
pain
Timepoint

Before inducing sedation and analge- After the procedure and complete awakining

Method of measurement

Visual analog scale(VAS)

2

Description

Hypertension

Timepoint

Before, during and immediately after the completion of procedure

Method of measurement

Electronic barometric(Saadat Factory)

3

Description

Heat rate

Timepoint

Before, during and immediately after the completion of procedure

Method of measurement

Electronic Monitor(Saadat Factory)

4

Description

SPO2

Timepoint

Before, during and immediately after the completion of procedure

Method of measurement

Electronic Pulsoximer(Saadat Factory)

5

Description

Respiratory rate

Timepoint

Before, during and immediately after the completion of procedure

Method of measurement

Clinical examination(Obsevation)

Secondary outcomes

1

Description

Apnea

Timepoint

during and immediately after the completion of procedure

Method of measurement

close observation

2

Description

bradycardia

Timepoint

during and immediately after the completion of procedure

Method of measurement

Electronic Monitor(Saadat Factory)

3

Description

Nausea and vomiting

Timepoint

during and immediately after the completion of procedure

Method of measurement

close obsevation

Intervention groups

1

Description

Intervention group: the first group, in this group midazolam (Darupakhsh Co, Iran) was given with dose of 0.1 mg /kg, and Fentanyl (Abu Rayhan CO, Iran),with dose of 3 µg/kg with with titarting dose until reaching the Ramsey sedation scale 5 .

Category

Treatment - Drugs

2

Description

Intervention group: The second group, in this group, dexmedethomidine (Huspiria of USA, Behestan Daroba) was given with a dose of 1 mg/kg with 10-minute intravenous infusion and fetanyl(Abu Ravihan Co, Iran) with a dose of 3 µg/kg with titrated dose until reaching to a Ramsey sedation scale of 5

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Immam Hosein hospital

Full name of responsible person

Ali Arhami Dolatabadi

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
ali arhami

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Ali Arhami Dolatabadi

Position
Associated professor of medical faculty

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable