Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing sedative effect of Midazolam injection by jet injector with intravenous Midazolam for diagnostic procedures in 1 to 6 years old children

Protocol summary

Summary

This study is a parallel single-blind randomized clinical trial comparing sedative effect of Midazolam injected by jet injector, with intravenous Midazolam for procedural sedation in children, 1 to 6 years old, presenting to the Emergency Department due to trauma. Patients eligible for the study, according to inclusion and exclusion criteria, are randomly allocated to two (30 person) groups after informed consent. Before the diagnostic procedure Midazolam is administered subcutaneously with the jet injector in the first group and intravenously through a peripheral catheter in the second group. Children are monitored for vital signs and level of consciousness before and during the sedation. When the patient reach the level 1 of sedation, the procedure is started. If the patient doesn't inter to the sedation phase, in the first group injection is repeated 20 min after the first injection and in the second group the administered dose is repeated every 3 min to reach the sedative effect or the maximum dose. Patient is monitored until he become alert and the time is recorded. Emergency department stay time is measured from the admission and discharge time and recorded. Eventually the parents and caring physician satisfaction from the procedure is evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510018640N2**
Registration date: **2016-03-23, 1395/01/04**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-03-23, 1395/01/04

Registrant information

Name

Majid Hajimaghsoudi

Name of organization / entity

Shahid Sadoughi University of Medical Scienses

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Recruitment status

Recruitment complete

Funding source

no funding source

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2016-07-04, 1395/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing sedative effect of Midazolam injection by jet injector with intravenous Midazolam for diagnostic procedures in 1 to 6 years old children

Public title

Efficacy of Midazolam on sedation

Purpose

Treatment

Inclusion/Exclusion criteria

Children 1-6 years old coming to Emergency Department due to trauma, requiring sedation for diagnostic procedures are included in the study. Those patients with one or more of the fallowing conditions are excluded: Unstable vital signs; Decreased level of consciousness; Anticonvulsants drug use; Hypersensitivity to Midazolam; Reluctance to participate in the study; Patients with moderate to severe (distracting) pain.

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Scienses

Street address

Shahid Sadoughi University of Medical Scienses Central Organizatio, Shahid Doctor Bahonar Square, Yazd

City

Yazd

Postal code

8916978477

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.SSU.MEDICINE.REC.1393.30

Health conditions studied

1

Description of health condition studied

Pediatric trauma

ICD-10 code

T14.9

ICD-10 code description

Injury nonspecified

Primary outcomes

1

Description

Success rate of sedation for prosedure

Timepoint

Emediately after the procedure

Method of measurement

Sedation scale (level 0: conscious- level 1: silence- level 2: drowsiness- level 3: snoozing- level 4: deep sleep)

Secondary outcomes

1

Description

Emergency department stay time

Timepoint

Before and after the intervention

Method of measurement

Time interval between admission and discharge from the emergency department

2

Description

Time to appropriate sedation

Timepoint

After the intervention

Method of measurement

Time interval between drug administration to level one of sedation

3

Description

Time to complete arrosal

Timepoint

After the intervention

Method of measurement

Time interval between drug administration to complete arrosal

4

Description

Failure of sedation

Timepoint

After the intervention

Method of measurement

Not reaching to the level one of sedation after administrating the maximum determined dose

5

Description

Physician satisfaction from sedation

Timepoint
After the intervention
Method of measurement
Five choice likert scale

6

Description
Parents satisfaction from sedation
Timepoint
After the intervention
Method of measurement
Five point likert scale

7

Description
Rate of complications
Timepoint
After the intervention
Method of measurement
Assessment of sign and symptoms of sedation complication

Intervention groups

1

Description
In the intervention group Midazolam is administered 0.2 mg/kg subcutaneously with the jet injector. If the patient doesn't inter to the sedation phase, injection is repeated 20 min after the first injection.
Category
Treatment - Drugs

2

Description
In the control group Midazolam is administered 0.1 mg/kg intravenously through a peripheral catheter. If the patient doesn't inter to the sedation phase, the administered dose is repeated every 3 min to reach the sedative effect or the maximum (0.6 mg/kg) dose.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Doctor Rahnemoon Hospital
Full name of responsible person
Majid Hajimaghsoudi
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Shahid Sdoughi Hospital, Ebne Sina Blvd, Shahid Ghandi Blvd, Safaieh, Yazd, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
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Amir Houshang Mehrparvar
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Shahid Sadougi University of Medical Scienses, Bahonar square, Yazd
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Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi 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
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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