

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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

2016-03-23, 1395/01/04

#### 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

#### Registrant information

##### Name

Majid Hajimaghsoudi

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8490 2719

##### Email address

hajimaghsoudi@tums.ac.ir

#### 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 following 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 Sciences

###### **Street address**

Shahid Sadoughi University of Medical Sciences  
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 enter 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 enter 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 Rahneemoon Hospital

##### Full name of responsible person

Majid Hajimaghsoudi

##### Street address

Farokhi St.

##### City

Yazd

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Sdoughi Hospital

##### Full name of responsible person

Majid Hajimaghsoudi

##### Street address

Shahid Sdoughi Hospital, Ebne Sina Blvd, Shahid Ghandi Blvd, Safaieh, Yazd, Iran

##### City

Yazd

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Full name of responsible person

Amir Houshang Mehrparvar

##### Street address

Shahid Sadougi University of Medical Sciences, Bahonar square, Yazd

##### City

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

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Full name of responsible person

Majid Hajimaghsoudi

##### Position

Assistant Professor of Emergency Medicine

##### Other areas of specialty/work

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Other areas of specialty/work**

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**Name of organization / entity**

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**Position**

Assistant Professor of Emergency Medicine

**Other areas of specialty/work**

**Street address**

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**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*