

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the sedative effect of two different doses of midazolam, 0.1mg/kg and 0.3mg/kg for brain CT-scan in children aged under 2 old years

Protocol summary

Summary

The aim of this study was to find the right dose of sedative drugs to achieve the appropriate level of sedation in children below 2 years who suffer from head trauma and require CT scan. Inclusion criteria was children below 2 years old and suffer from head trauma. Exclusion criteria were anticipated difficult airway; history of adverse reactions to benzodiazepines; hemodynamic instability ... This clinical trial conducted on 120 children below 2 years. In this study, two different doses of intravenous administration of midazolam (0.1mg / kg and 0.3mg / kg) in two 60-member groups were compared with each other. Variables include the mean score of Ramsay, duration and effect of sedative drugs, oxygen saturation, respiratory rate and pulse rate and complications. Children were enrolled to study who had three sedation level or higher, after administration of midazolam. Additional doses of midazolam will administrated five minutes later in cases with not desired level of sedation, and if no response haven't observed, ketamine will administrated. Then the studied variables were analyzed in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092121289N2**
Registration date: **2015-11-01, 1394/08/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-01, 1394/08/10

Registrant information

Name

Akram Rohani Marvasti

Name of organization / entity

Ahvaz, Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research Center of Ahvaz Jundishapur University of Medical Sciences Faculty of Medicine

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the sedative effect of two different doses of midazolam, 0.1mg/kg and 0.3mg/kg for brain CT-scan in children aged under 2 old years

Public title

Comparison medicinal doses of midazolam in sedation of children under 2 years for brain CT scan

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children under 2 years old; suffered from head trauma; and have permission to do brain CT scan. Exclusion criteria include anticipated difficult airway; history of adverse reactions to benzodiazepines; hemodynamic instability; congestive heart failure; liver disease; impaired level of consciousness (defined as a Glasgow coma scale less than 15); uncontrolled vomiting; gastric esophageal reflux history; concomitant use of drugs and uremia.

Age

From **1 day** old to **2 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences
Faculty of Medicine

Street address

Khuzestan, Ahvaz, Iran - Golestan highway - opposite the Khuzestan Water and Power Authority (five classes) - the main door of Ahvaz University of Medical Sciences and Health Services

City

ahvaz

Postal code

6135715794

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

GP93044

Health conditions studied

1

Description of health condition studied

Sedation of children for CT scan

ICD-10 code

Z00.0, Z00

ICD-10 code description

General medical examination, Routine child health examination

Primary outcomes

1

Description

Ramsay sedation score (RSS)

Timepoint

Initiation of intervention

Method of measurement

Ramsay sedation score (RSS)

Secondary outcomes

1

Description

Duration and impact of sedation medication

Timepoint

first day

Method of measurement

Monitor and measure

2

Description

Oxygen saturation

Timepoint

first day

Method of measurement

Measurement of arterial blood gases

3

Description

respiratory and pulse rate

Timepoint

first day

Method of measurement

Monitor and measure

4

Description

complications

Timepoint

The first day until the seventh day

Method of measurement

Monitor and measure

Intervention groups

1

Description

Patients in the first group a dose of 0.1 mg / kg intravenous midazolam were injected during the study, children at a dose of midazolam 0.1mg / kg and 0.3mg / kg for them, was not sufficient to perform process, injection up to a maximum of 3 times was performed. Interval between doses was at least 5 minutes.

Category

Treatment - Drugs

2

Description

Patients in the second group, a dose of 0.3 mg / kg intravenous midazolam were injected during the study, children at a dose of midazolam 0.1mg / kg and 0.3mg / kg for them, was not sufficient to perform process, injection up to a maximum of 3 times was performed. Interval between doses was at least 5 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Shima Zeynoddini

Street address

City

ahvaz

2

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Shima Zeynoddini

Street address

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

research deputy of Ahvaz Jundishapur University of Medical Sciences Faculty of Medicine

Full name of responsible person

Nader Saki

Street address

The main door of Ahvaz University of Medical Sciences and Health Services- opposite the Khuzestan Water and Power Authority (five classes)- Golestan highway- Ahvaz- Khuzestan- Iran

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ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

research deputy of Ahvaz Jundishapur University of Medical Sciences Faculty of Medicine

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

Ahvaz Jundishapur University of Medical Sciences Faculty of Medicine

Full name of responsible person

Hasan Barzegar

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Ahvaz Jundishapur University of Medical Sciences
Faculty of Medicine

Full name of responsible person

Shima Zeinodini

Position

resident of Emergency Medicine

Other areas of specialty/work

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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