

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of oral sedation with midazolam and promethazine compared with midazolam in children less than 7 years old undergoing CT-scan

Protocol summary

Summary

The purpose of this study is to compare the safety and efficacy of oral midazolam and midazolam-promethazine combination to sedate children less than 7 years old undergoing CT-scan. We evaluated efficiency of them based on age and sex and weight, sedation scores, onset and duration of sleep and hemodynamic changes. children aged less than 7 years who who scheduled for CT scan and are placed under sedation enter this study and if there are history of allergy to the ingredients used or having neurological or vascular defects excluded. Children who entered this study are randomly allocate into two groups: Group P receive oral promethazine (1.25 mg.kg-1) with midazolam (0.5 mg.kg-1), and Group M receive oral placebo with midazolam (0.5 mg.kg-1) alone. Sedation scores, onset and duration of sleep are evaluate. Adverse effects, including hypoxemia, failed sedation, and the return of based activity, will documented. Statistical analysis is performed with spss software

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202279148N1**

Registration date: **2013-01-21, 1391/11/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-21, 1391/11/02

Registrant information

Name

Hassan Barzegari

Name of organization / entity

Golestan Hospital

Country

Iran (Islamic Republic of)

Phone

+98 61 1374 3079

Email address

barzegari-h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahwaz Jundi Shapur University Of Medical Sciences

Expected recruitment start date

2011-09-21, 1390/06/30

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of oral sedation with midazolam and promethazine compared with midazolam in children less than 7 years old undergoing CT-scan

Public title

comparison of oral promethazine plus oral midazolam and oral midazolam in children sedation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: children aged less than 7 years who were scheduled for CT scan and are placed under sedation
Exclusion criteria: history of allergy to the ingredients used - having neurological defects and vascular defects

Age

To **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 46

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**Research and Technology Department of Ahwaz
Jondishapur University Of Medical Sciences**Street address**

Ahwaz Jondishapur University Of Medical Sciences

City

Ahwaz

Postal code**Approval date**

2010-08-20, 1389/05/29

Ethics committee reference number

ETH-371

Health conditions studied**1****Description of health condition studied**

sedation

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

onset and duration of sleep

Timepoint

Continuously until the onset of drug effects

Method of measurement

observe of the patient and determine the level of

consciousness

Secondary outcomes**1****Description**Heart rate - Respiratory rate - blood pressure - oxygen
saturation of arterial blood**Timepoint**

Every 5 minutes from start to finish drug effects

Method of measurementbeats per minute - respiratory per minute - mm Hg -
percent**Intervention groups****1****Description**Intervention group: they will be receive syrup
promethazine 1.25 mg/kg orally one hour before the CT
scan is done. Then a dose of 0.5mg/kg oral midazolam
20 minutes before CT (mixed with fruit juice) is given.If
vomiting occurs within 15 minutes of administration of
midazolam, we again repeat the dose. Children who do
not sleep 30 minutes after midazolam administration
50% of the initial dose of midazolam should take to
complete.**Category**

Treatment - Drugs

2**Description**control group: they will be receive Sugar syrup 0.5 mg/kg
orally one hour before the CT scan is done. Then a dose
of 0.5mg/kg oral midazolam 20 minutes before CT
(mixed with fruit juice) is given.If vomiting occurs within
15 minutes of administration of midazolam, we again
repeat the dose. Children who do not sleep 30 minutes
after midazolam administration 50% of the initial dose of
midazolam should take to complete.**Category**

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan Hospital

Full name of responsible person

Dr. Hassan Barzegari

Street address

Ahwaz Jondishapur University Of Medical Sciences

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz Jondishapur University Of Medical Sciences

Full name of responsible person

Ahwaz Jondishapur University Of Medical Sciences

Street address

Ahwaz Jondishapur University Of Medical Sciences

City

Ahwaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahwaz Jondishapur 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**

Ahwaz Jondishapur University Of Medical Sciences

Full name of responsible person

Dr. Hassan Barzegari

Position

Emergency Medicine Specialist / Assistant Professor

Other areas of specialty/work**Street address**

Ahwaz Jondishapur University Of Medical Sciences

City

Ahwaz

Postal code**Phone**

+98 61 1374 3079

Fax**Email**

h_b1979@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ahwaz Jondishapur University Of Medical Sciences

Full name of responsible person

Dr Hassan Barzegari

Position

Emergency Medicine Specialist /Assistant Professor

Other areas of specialty/work**Street address**

Ahwaz Jondishapur University Of Medical Sciences

City

Ahwaz

Postal code**Phone**

+98 61 1374 3079

Fax**Email**

h_b1979@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Ahwaz Jondishapur University Of Medical Sciences

Full name of responsible person

Dr. Hassan Barzegari

Position

Emergency Medicine Specialist /Assistant Professor

Other areas of specialty/work**Street address**

Ahwaz Jondishapur University Of Medical Sciences

City

Ahwaz

Postal code**Phone**

+98 61 1374 3079

Fax**Email**

h_b1979@yahoo.com

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