

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effectiveness of oral ketamin,Midazolam and Atropine cocktail versus oral Diphenhydramin for pediatric Sedation in Emergency Department

Protocol summary

Summary

In a randomized double-blind prospective clinical trial performed in Imam Reza Hospital Emergency Department, 80 infants and children aged 2-10 years with wounds requiring local anesthesia for performing sutures will be included. Prior to the study, parental written informed consents will be obtained. Sampling will be performed confidentially and randomly. Patients will be divided into groups 1 and 2 as follows: Group 1: patients having received oral diphenhydramine for sedation. Group 2: patients having received oral ketamine, midazolam, and atropine for sedation. Medicine acceptance by the child and his/her anxiety will be registered via questioning the parents. If local anesthesia is required, those with anxiety scale of more than 1 will enter the study. Infiltration of the local anesthetic will be registered based on the tranquility degree every 5 minutes. For scores more than 4, or at least 45 minutes later, the tranquilizer will be administered. After the patient sitting on the examination bed, nasal mask will be placed. Consciousness status of the patient will be monitored regularly. All the oral administration of the medicines will be performed under the supervision of an emergency medicine. All behavioral patterns of the child including cry, consciousness, and movement throughout the procedure will be registered and evaluated based on the Houpt scale by a third colleague. In addition to the evaluation of the behaviors of the child, treatment will be performed based on the Houpt scale. After two weeks from the hospital discharge, the probable behavioral changes within two weeks will be registered via telephone connection with the parents. The obtained data will be analyzed using SPSS 16 and to the study the relation between the variables, Chi-square and Mann-Whitney U test will be used. A P value less than 0.05 will be considered statistically significant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212312496N8**

Registration date: **2013-01-03, 1391/10/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-01-03, 1391/10/14

Registrant information

Name

Hassan Soleimanpour

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1329 1286

Email address

soleimanpourh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research-Vice chancellor, Tabriz University of Medical Sciences, Iran

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-07-21, 1392/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of oral ketamin, Midazolam and Atropine cocktail versus oral Diphenhydramin for pediatric Sedation in Emergency Department

Public title

Effectiveness of oral ketamin, Midazolam and Atropine cocktail versus oral Diphenhydramin for pediatric Sedation in Emergency Department

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Children aged 2-10 years having referred to the emergency department for wound stitches requiring local anesthesia prior to the procedure. Exclusion criteria: Patients with the history of psychologic or mental disorders, children with attention deficit-hyperactivity disorder, multiple traumas, GCS<15, common cold, unwillingness of the parents to take part in the study, illiterate parents, known allergy, prior history of erythromycin administration, chronic underlying diseases such as convulsive disorders, patients with lower-extremity ulcers, mucosal ulcers, wounds larger than 4 centimeters or with the depth of more than 0.5 centimeters and single ulcers, too.

Age

From **2 years** old to **10 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Research Vice chancellor of Tabriz University of Medical Sciences

Street address

Research Vice chancellor of Tabriz University of Medical Sciences, Tabriz University of Medical

Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN.

City

Tabriz

Postal code**Approval date**

2012-06-25, 1391/04/05

Ethics committee reference number

9154

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

sedation during procedure

ICD-10 code

T88.52

ICD-10 code description

sedation(conscious) (moderate) during procedure

Primary outcomes**1****Description**

sedation

Timepoint

Every 5 minutes to 45 minutes after administration of sedatives

Method of measurement

Grade 1: drowsiness, the patient needs a stimulus for waking up- Grade 2: drowsiness, the eyes are closed and patient needs a mild verbal or touch stimulus for waking up- Grade 3: drowsiness, the eyes are open but the eye responsiveness has reduced to low activity- Grade 4: complete awakeness- Grade 5: complete agitation

Secondary outcomes**1****Description**

All behavioral patterns of the child including cry, consciousness, and movement throughout the procedure

Timepoint

When local anesthetic injecting and during the procedure

Method of measurement

Based on the Houpt scale

Intervention groups**1****Description**

Oral Diphenhydramin : 0.5mg/kg

Category

Prevention

2**Description**

Oral ketamin(6mg/kg), Midazolam(0.05mg/kg) and Atropine(0.02mg/kg) cocktail

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza hospital

Full name of responsible person

Dr.Hassan Soleimanpour

Street address

Emergency Medicine Department, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN. Tabriz

City

Tabriz

Full name of responsible person

Dr.Hassan Soleimanpour

Position

Anesthesiologist/ Associate professor of Anesthesiology, MD

Other areas of specialty/work

Street address

Emergency Medicine Department, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN. Tabriz

City

Tabriz

Postal code

51664

Phone

+98 41 1335 2078

Fax

Email

h_mofid1357@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice chancellor of Tabriz University of Medical Sciences

Full name of responsible person

Dr.seyed kazem shakouri

Street address

Research Vice chancellor of Tabriz University of Medical Sciences ,Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Vice chancellor of Tabriz 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

Tabriz University of Medical Sciences

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Hassan Soleimanpour

Position

Anesthesiologist/ Associate professor of Anesthesiology, MD

Other areas of specialty/work

Street address

Emergency Medicine Department, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz-51664, I.R IRAN. Tabriz

City

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Postal code

51664

Phone

+98 41 1335 2078

Fax

+98 41 1335 2078

Email

h_mofid1357@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Hassan Soleimanpour

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Medical Sciences, Daneshgah Street, Tabriz-51664,
I.R IRAN. Tabriz

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Fax

+98 41 1335 2078

Email

h_mofid1357@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