

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Clonazepam and Lorazepam in the Treatment of Methamphetamine-Poisoned Children

Protocol summary

Study aim

Comparison of Clonazepam and Lorazepam in the Treatment of methamphetamine-Poisoned Children

Design

single blind, parallel group randomized-controlled clinical trial with 30 cases are divided into 2 groups of oral Clonazepam or Lorazepam according to the random numbers each of them include 15 case.

Settings and conduct

In this double blind, randomized-controlled clinical trial, which is done to investigate the effect of oral benzodiazepin (Clonazepam or Lorazepam), in children under 12 year-old with methamphetamine poisoning who presented to pediatrics emergency department, Loghman Hakim hospital, Iran, according to the inclusion and exclusion criteria. After filling the permission form with parents according to the random numbers software, 30 patients are divided into 2 groups of fifteen. After initial administration of 0.2-mg/Kg intravenous Diazepam, oral benzodiazepines (0.05 mg/kg Clonazepam or Lorazepam) were only given once to prevent return of stimulant toxicity. Oral benzodiazepines were given when the patient was calm, and could be switched to oral regimen. Vital signs and clinical symptoms are recorded Upon arrival then every 6 hours.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children under 12-year-old age with methamphetamine poisoning exclusion criteria: Multiple-drug poisoning

Intervention groups

After initial administration of 0.2-mg/Kg intravenous Diazepam, oral benzodiazepines (0.05 mg/kg Clonazepam or Lorazepam) were only given once to prevent return of stimulant toxicity. Oral benzodiazepines were given when the patient was calm, and could be switched to oral regimen.

Main outcome variables

Agitation level; duration of hospital stay; side effects of treatment (respiratory depression, deep sedation, paradoxical agitation).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180610040036N2**

Registration date: **2020-04-18, 1399/01/30**

Registration timing: **retrospective**

Last update: **2020-04-18, 1399/01/30**

Update count: **0**

Registration date

2020-04-18, 1399/01/30

Registrant information

Name

Narges Gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4442 7956

Email address

nargesgholami@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

2017-01-01, 1395/10/12

Actual recruitment end date

2018-01-02, 1396/10/12
Trial completion date
2018-01-20, 1396/10/30
Scientific title
Comparison of Clonazepam and Lorazepam in the Treatment of Methamphetamine-Poisoned Children

Public title
" Clonazepam and Lorazepam in methamphetamine poisoning"

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Methamphetamine-Poisoned Children under 12-year-old age
Exclusion criteria:
multiple-drug poisoning

Age
From **6 months** old to **144 months** old

Gender
Both

Phase
4

Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
First, a framework was made of numbers 1-30 , then the assignment of these numbers to group 1-2 was determined based on the random numbers table. A computer software program (www.random.org) was used to produce random numbers to allocate the medication (Clonazepam or Lorazepam) to 2 groups. Adequate medications for each group were be placed in a envelope marked with patient number and medication code.

Blinding (investigator's opinion)
Single blinded

Blinding description
After filling the permission form with parents, care giver divides the patients according to the random numbers and random numbers generator software into 2 groups and parents are not aware of the type of intervention. Nurse provider prescribes a medicine (0.05 mg/kg Clonazepam or Lorazepam) placed in the same drug-envelope and placed inside the envelope with the code assigned to each patient after initial administration of 0.2-mg/Kg intravenous Diazepam . Outcome assessor write the intervention and data is entered into the questionnaire based on the code of each person. Data analyser analysed final data bu SPSS software.

Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti university of medical sciences

Street address

Kodakyar st , Shahriary Sq , Chamran High way

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2016-08-28, 1395/06/07

Ethics committee reference number

IR.SBMU.RETECH.REC.1394.122

Health conditions studied

1

Description of health condition studied

Methamphetamine poisoning

ICD-10 code

F15.12

ICD-10 code description

Other stimulant abuse with intoxication

Primary outcomes

1

Description

Agitation level

Timepoint

Admission time, 6,12,18,24 hours

Method of measurement

questionnaire (Richmond Agitation)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Oral Clonazepam

Category

Treatment - Drugs

2

Description

Intervention group 2: Oral Lorazepam

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim hospital

Full name of responsible person

Fariba Farnaghi

Street address

Loghman hospital.Kargar st

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Postal code

1333625445

Phone

+98 21 5102 5182

Email

faribafarnaghi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hossein Hassanian-Moghaddam

Position

Associate professor of clinical toxicology

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

En Final data has been given to Vice-Chancellor of Research Affairs of Shahid Beheshti University of Medical Sciences

When the data will become available and for how long

19.2.2018 -19.2.2021

To whom data/document is available

Pediatrics, Clinical toxicology flow ship

Under which criteria data/document could be used

All researchers are allowed to receive data details and protocols according professional ethics

From where data/document is obtainable

Contact with authors

What processes are involved for a request to access data/document

By email to author(faribafarnaghi@yahoo.com). It takes about 7 days.

Comments