Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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.

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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 Lorazapam) 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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Tehran
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1333625445
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+98 21 5102 5182
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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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1985717434
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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
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Position
Associate professor of clinical toxicology
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Person responsible for updating data

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Full name of responsible person
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Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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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