

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of magnesium sulfate in patients with tricyclic anti depressant to reduce mortality rates

Protocol summary

Summary

The purpose of this study was to investigate the therapeutic effects of magnesium sulfate in patients with tricyclic antidepressants. The study population was the patients referred to emergency ward of Loghman Hakim Poison hospital with history of TCA poisoning. A total of 72 patients were randomized into. The patients in the control group received sodium bicarbonate but in the intervention group received Sodium Bicarbonate as well as Magnesium Sulfate %20, 1 gram IV every 6 hours. Mortality rate and hospital stay was measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811142717N1**
Registration date: **2010-05-29, 1389/03/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-29, 1389/03/08

Registrant information

Name

Babak Mostafazadeh

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5540 9534

Email address

mstzbmd@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shaheed Beheshti University of Medical sciences

Expected recruitment start date

2009-03-01, 1387/12/11

Expected recruitment end date

2010-02-20, 1388/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of magnesium sulfate in patients with tricyclic anti depressant to reduce mortality rates

Public title

Effects of magnesium sulfate in patients poisoned with tricyclic antidepressants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: TCA poisoning with more than 20mg/kg TCA, Widening QRS> 12msec, PH<7.2, and/or presence of convulsion Exclusion criteria: The other causes of seizures, including trauma, tramadol poisoning, Hypoglycemia, ECG findings due to ischemic heart disease

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shaheed Beheshti university of Medical sciences

Street address

Shaheed Beheshti university of Medical sciences,
Tehran

City

Tehran

Postal code**Approval date**

2009-02-02, 1387/11/14

Ethics committee reference number

87-01-113-5738

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

TCA poisoning

ICD-10 code

T43.0

ICD-10 code description

Tricyclic and tetracyclic antidepressants

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

Mortality rate

Timepoint

6 h and 24h after admission and discharge time

Method of measurement

mortality rate

2**Description**

Admission days

Timepoint

discharge time

Method of measurement

Hospital Recording

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

Morbidity rate

Timepoint

every week

Method of measurement

Clinical assesment

2**Description**

Complications of admission

Timepoint

every week

Method of measurement

Clinical assesment

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

Sodium bicarbonate, 88 milliequivalent, IV, single dose at the begining of treatment

Category

Treatment - Drugs

2**Description**

Sodium bicarbonate with 88 milliequivalent IV, single dose at the begining of treatment as well as Magnesium Sulfate 20%, 1 gram IV, every 6 hours for 4 doses

Category

Treatment - Drugs

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

Loghman Hakim Hospital

Full name of responsible person

Babak Mostafazadeh

Street address**City**

Tehran

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Shahid Beheshti University of Medical Sciences
Full name of responsible person
 Dr. Babak Mostafazadeh
Street address
 Shahid Beheshti University of Medical Sciences,
 Tehran
City
 Tehran
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
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
 Shahid Beheshti University of Medical Sciences
Full name of responsible person
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 Assistant Professor, Medical Toxicology and Forensic
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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