

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of therapeutic effects of bicarbonate and bicarbonate plus intravenous lipid emulsion in tricyclic antidepressants toxicity

Protocol summary

Summary

Tricyclic antidepressants (TCA) toxicity is one of the major causes of drug toxicity all over the world, which can cause severe cardiac and neurological effects and even mortality. Some experimental animal studies have shown that intravenous lipid emulsions can be helpful in treatment of TCA toxicity, and some case reports also confirmed these results. We are trying to find out whether intralipid do have a place in treatment of TCA toxicity. For this purpose, 108 patients with severe TCA toxicity who are visiting The Loghman Hospital (a referral toxicology center) will be randomly divided to intervention and control group. The control group would receive the standard treatment with bicarbonate and the intervention would receive standard treatment plus intravenous lipid emulsion. The outcomes that will be compared between these two groups are the time that EKG and blood pressure become normal and final mortality and morbidity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012061610017N2**

Registration date: **2012-07-24, 1391/05/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-24, 1391/05/03

Registrant information

Name

Hamed Basir Ghafouri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-04-25, 1391/02/06

Expected recruitment end date

2012-08-25, 1391/06/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects of bicarbonate and bicarbonate plus intravenous lipid emulsion in tricyclic antidepressants toxicity

Public title

Therapeutic effects of intravenous lipid emulsion in tricyclic antidepressants toxicity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with TCA toxicity according to patient history by himself or other sources of history, who are over 16 and have the indication for starting bicarbonate therapy. Exclusion criteria: patients with renal failure; pulmonary edema; brain edema; toxication with carbamazepine or phenothiazine in addition to TCA.

Age

From **16 years** old

Gender

Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **108**

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

Research ethics committee of Tehran University of medical sciences

Street address

Headquarter for Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2012-04-20, 1391/02/01

Ethics committee reference number

130/2830/90/3

Health conditions studied

1

Description of health condition studied

Tricyclic antidepressants toxicity

ICD-10 code

T43.0

ICD-10 code description

Poisoning by psychotropic drugs, not elsewhere classified/Tricyclic and tetracyclic antidepressants

Primary outcomes

1

Description

Normalization time for blood pressure

Timepoint

Minutes of 30, 60, 90, 240, 480 and 720

Method of measurement

Patients' blood pressure would be detected by mercury barometer in mmHg and the time that blood pressure reach above 90 mmHg will be noted.

2

Description

Normalization time for EKG

Timepoint

Minutes of 30, 60, 90, 240, 480 and 720

Method of measurement

Checklists to be filled by the patients physician

Secondary outcomes

1

Description

Final mortality and morbidity

Timepoint

At the patient discharge time

Method of measurement

Observation

Intervention groups

1

Description

Control: standard treatment of TCA toxicity which contains GI decontamination, fluid resuscitation, and intravenous bicarbonate.

Category

Treatment - Drugs

2

Description

Intervention: standard treatment of TCA toxicity which contains GI decontamination, fluid resuscitation, and intravenous bicarbonate plus 100 cc intravenous lipid emulsion 20% in 1 min and 400 cc in 20 min.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Shahin Akhundzadeh

Street address

First floor (No.303), School of medicine, Tehran
University of Medical Sciences, Pur sina street,
Keshavarz Blvd.

City

Tehran

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

Yes

Title of funding source

Tehran 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**

School of medicine, Tehran University of Medical
Sciences

Full name of responsible person

Dr. Movahedi Behnam

Position

Emergency Medicine resident

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

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Person responsible for updating data

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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