

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Effect of Flumazenil Drip On Speed Of Recovery And Prevention Of Complications In Severe Acute Benzodiazepine Toxicity

Protocol summary

Study aim

Effect of flumazenil drip on speed of recovery and complications in severe acute benzodiazepine toxicity

Design

In this phase 2-3 single-blind clinical trial, a total of 50 patients with severe benzodiazepine poisoning in need of intubation are included. They are randomly assigned into 2 groups (receiving loading dose of flumazenil followed by conservative treatment versus continuous infusion of flumazenil). The data is analyzed by SPSS 21.

Settings and conduct

Between 2018 and 2019, 50 patients referring to Lohman Hakim toxicology ED with severe benzodiazepine toxicity are assigned into the case (those who will receive a flumazenil drip after the loading dose of flumazenil) and control (those who only receive conservative management after single loading dose of flumazenil). Patients undergo intubation if needed and receive the conservative management. In the control group, a flumazenil drip of at least 200 µg/h is initiated. The dose, however, is measured then increased or decreased based upon the patients' clinical characteristics and need. The drip dose is actually titrated to maintain the patients' consciousness acceptable (14 or 15).

Participants/Inclusion and exclusion criteria

A total of 50 severely benzodiazepine-poisoned patients (in need for intubation) are included. Those with abnormal vital signs on presentation, history of seizure, ingestion or use of any drug/medication that can precipitate seizure, head trauma, possible brain edema and increased intracranial pressure, and hypoxemia are excluded.

Intervention groups

Intervention group: treated by administration of flumazenil drip (initial dose of 200 microgram/hour).
Control group: routine conservative care

Main outcome variables

Mortality- Complications during treatment- Need for

intubation after initial response to flumazenil

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120629010133N3**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **retrospective**

Last update: **2020-05-31, 1399/03/11**

Update count: **0**

Registration date

2020-05-31, 1399/03/11

Registrant information

Name

Hossein Hassanian-Moghaddam

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5542 4041

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hassanian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

2018-05-25, 1397/03/04

Actual recruitment end date

2019-10-22, 1398/07/30

Trial completion date

2019-10-22, 1398/07/30

Scientific title

Effect of Flumazenil Drip On Speed Of Recovery And Prevention Of Complications In Severe Acute Benzodiazepine Toxicity

Public title

Effect of Flumazenil Drip On Speed Of Recovery And Prevention Of Complications In Severe Acute Benzodiazepine Toxicity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Severely benzodiazepine-poisoned patients (in need for intubation and mechanical ventilation) with otherwise normal vital signs

Exclusion criteria:

Abnormal vital signs on presentation, history of seizure, history of ingestion or use of any drug/medication that can predispose the patient to seizure, history of head trauma, possible brain edema and increased intracranial pressure, history of hypoxemia

Age

From 12 years old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: 50

Actual sample size reached: 50

Randomization (investigator's opinion)

Not randomized

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

Single blinded

Blinding description

Patients are blind to receive flumazenil drip or not

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shahid Beheshti University of Medical Sciences Ethics Committee

Street address

Yaman Street- Velenjak

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2018-03-05, 1396/12/14

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.428

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

Benzodiazepine poisoning

ICD-10 code

T42.0

ICD-10 code description

Poisoning by, adverse effect of and underdosing of hydantoin derivatives

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

Mortality-

Timepoint

7 days after admission

Method of measurement

Observation and questionnaire recording

2**Description**

Complications during hospitalization

Timepoint

7 days after admission

Method of measurement

Observation and questionnaire recording

3**Description**

Intubation

Timepoint

7 days after admission

Method of measurement

Observation and questionnaire recording

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

Hospitalization period

Timepoint

At discharge or death

Method of measurement

Observation and questionnaire recording

Intervention groups

1

Description

Intervention group: Administration of flumazenil drip (initial dose of 200 micro per hour and its adjustment based on patient's situations) followed by its tapering

Category

Treatment - Drugs

2

Description

Control group: are the patients who do not receive maintenance dose of flumazenil and are only followed and treated conservatively.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital-Poisoning Ward

Full name of responsible person

Hossein Hassanian-Moghaddam

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Lashgar Street- Sout Karegar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

NIMAD (National Institute for Medical Research Development)

Full name of responsible person

Reza Malekzadeh

Street address

West Fatemi Street

City

Tehran

Province

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Postal code

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Email

NIMAD@RESEARCH.AC.IR

Web page address

http://nimad.ac.ir/index.php?sid=1&slct_pg_id=25&slc_lang=fa

Grant name

Grant code / Reference number

971196

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

Yes

Title of funding source

NIMAD (National Institute for Medical Research Development)

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

Other

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

Attending Physician

Latest degree

Medical doctor

Other areas of specialty/work

Toxicology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Attending Physician

Latest degree

Specialist

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after elimination of the patient information

When the data will become available and for how long

September 2020

To whom data/document is available

Researchers

Under which criteria data/document could be used

With the condition of mentioning the recourse

From where data/document is obtainable

Main Researchers Email

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

Emailing the main researcher

Comments