

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of zolpidem and amantadine on the level of consciousness in patients diffuse axonal injury

Protocol summary

Study aim

Comparison of the effect of zolpidem and amantadine on the level of consciousness in patients with diffuse axonal injury: a randomized clinical trial study

Design

A randomized controlled clinical trial with parallel groups, randomized, using Random allocation software

Settings and conduct

This study was performed on 66 patients with vegetable status approved by a neurosurgeon, as well as written consent from their fellows, who were randomly divided into 3 groups. The first group received 10 mg of Zolpidem daily for 8 days in the first group and the second group received 100 mg of amantadine capsule daily for 8 days. The third is given placebo daily for 8 days and during these 8 days up to 3 days after discontinuation of the medication the patients' consciousness status is monitored daily through Glasgow grade is evaluated and then all three groups are compared. Assistant Neurosurgery Assistant Knows No Patient Grouping

Participants/Inclusion and exclusion criteria

1. Confirmation of axonal injury published by a specialist in neurosurgery. 2. GCS less than or equal to 8 3. Age between 15 and 70 years 4. Hospitalized less than 8 hours after injury 5. Informed consent from the patient's companions for inclusion in the study Exit 1. Patient's or guardian's dissatisfaction with the study 2. A history of drug allergy to zolpidem or amantadine 3. History of any previous brain trauma 4. History of any previous brain procedure

Intervention groups

The first group is given 8 mg of Zolpidem Tablets daily for 8 days and the second group is given 100 mg Amantadine capsule daily for 8 days.

Main outcome variables

Increased level of consciousness in patients with diffuse axonal injury

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191026045243N1**

Registration date: **2019-11-26, 1398/09/05**

Registration timing: **prospective**

Last update: **2019-11-26, 1398/09/05**

Update count: **0**

Registration date

2019-11-26, 1398/09/05

Registrant information

Name

Sajad Shafiee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1630

Email address

sajad.shafiee@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of zolpidem and amantadine on the level of consciousness in patients diffuse axonal injury

Public title

The effect of zolpidem and amantadine on the level of consciousness in patients diffuse axonal injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Confirmation of axonal injury published by a specialist in neurosurgery 2. GCS less than or equal to 8 3. Age between 15 and 70 years 4. Hospitalized less than 8 hours after injury 5. Informed consent from the patient's companions for inclusion in the study

Exclusion criteria:

1. Patient's or guardian's dissatisfaction with the study 2. A history of drug allergy to zolpidem or amantadine 3. History of any previous brain trauma 4. History of any previous brain procedure

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, 66 patients with inclusion criteria will be selected by available sampling method and then these samples will be divided into 3 groups using blocking method. The block allocation process will be done using Random allocation software. The block size will also be random.

Blinding (investigator's opinion)

Single blinded

Blinding description

The first group received Zolpidem 10 mg daily for 8 days, the second group received 100 mg Amantadine capsule daily for 8 days, and the third group received 8 mg daily. Daily, placebo is given daily and during these 8 days and up to 3 days after discontinuation of the medication, patients' consciousness status is assessed daily by the Glasgow Critical Assistant, Neurosurgery Assistant.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Imam Khomeini Hospital of Sari - Mazandaran University of Medical Sciences

Street address

Amir Mazandarani Blvd

City

Sari

Province

Mazandaran

Postal code

48166-33131

Approval date

2019-08-19, 1398/05/28

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1398.119

Health conditions studied

1

Description of health condition studied

diffuse axonal injury

ICD-10 code

G35-G37

ICD-10 code description

بیماریهای از بین برنده میلین در سیستم عصبی مرکزی

Primary outcomes

1

Description

Increased awareness and speed of recovery for patients with cognitive problems and brain injuries

Timepoint

During these 8 days and up to 3 days after discontinuation of the drug

Method of measurement

Glasgow Coma Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group received 10 mg of Zolpidem daily for 8 days and the second group received 100 mg of amantadine capsule daily for 8 days.

Category

Treatment - Drugs

2

Description

Control group: The third group received placebo daily for 8 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Sari

Full name of responsible person

Sajad Shafiee

Street address

Amir Mazandarani Blvd

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Email

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Web page address

https://fa.irc.t.ir/user/trial/43503/update/recruitment_center

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Sajad Shafiee

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Web page address

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Sajad Shafiee

Position

Scientific Assistant

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Scientific Assistant

Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Sajad Shafiee

Position

Scientific Assistant

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Amir Mazandarani Blvd

City

Sari

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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