

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The comparison between oral modafinil and placebo to accelerate the rate of improvement in the level of consciousness in adult patients with moderate or severe acute traumatic brain injury admitted in intensive care units of Rajae Trauma Center in 1399-1400

Protocol summary

Study aim

The comparison between oral modafinil and placebo to accelerate the rate of improvement in the level of consciousness in adult patients with moderate or severe acute traumatic brain injury admitted in intensive care units

Design

Double-blind randomized clinical trial

Settings and conduct

Intervention group: Patients in the drug group receive 200 mg of oral modafinil daily (Torrent Pharma, UK) at 9 am. Control group: In order not to inform patients, physicians, nurses and the entire treatment team about assigning patients to two groups, placebo is prepared with the help of the pharmacosynthetic department of the School of Pharmacy in a completely similar way in terms of color, size and weight .patients receive the placebo at 9 am.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients who have a GCS score between 6 and 12 at the time of initiation of NG tube feeding in the ICU, Head AIS score above 3 on the first day of ICU stay, the AIS score of the other parts below 3 on the first day of ICU stay, Age over 18 years and under 70 years, Patients with moderate or severe head injury who are admitted to intensive care. Exclusion Criteria: Severe side effects such as severe agitation or anaphylactic reaction to modafinil ,Occurrence of seizures, Incidence of death or brain death, multiple trauma, Injury Severity Score less than 20.

Intervention groups

Intervention group: Patients in the drug group receive 200 mg of oral modafinil daily (Torrent Pharma, UK) at 9 am. Control group: In order not to inform patients, physicians, nurses and the entire treatment team about assigning patients to two groups, placebo is prepared

with the help of the pharmacosynthetic department of the School of Pharmacy in a completely similar way in terms of color, size and weight .patients receive the placebo at 9 am.

Main outcome variables

Unawareness condition, Agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N105**

Registration date: **2021-01-25, 1399/11/06**

Registration timing: **prospective**

Last update: **2021-01-25, 1399/11/06**

Update count: **0**

Registration date

2021-01-25, 1399/11/06

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-02, 1399/11/14
Expected recruitment end date
2022-03-05, 1400/12/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The comparison between oral modafinil and placebo to accelerate the rate of improvement in the level of consciousness in adult patients with moderate or severe acute traumatic brain injury admitted in intensive care units of Rajae Trauma Center in 1399-1400

Public title

The comparison between oral modafinil and placebo to accelerate the rate of improvement in the level of consciousness in adult patients with moderate or severe acute traumatic brain injury admitted in intensive care units of Rajae Trauma Center in 1399-1400

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have a GCS score between 6 and 12 at the time of initiation of NG tube feeding in the ICU Head AIS score above 3 on the first day of ICU stay, the AIS score of the other parts below 3 on the first day of ICU stay, the consent of the patient's guardian or legal guardian Consent of the patient's guardian or legal guardian Age over 18 years and under 70 years Patients with moderate or severe head injury who are admitted to intensive care

Exclusion criteria:

Severe side effects such as severe agitation or anaphylactic reaction to modafinil Occurrence of seizures Incidence of death or brain death multiple trauma Injury Severity Score less than 20 History of psychotropic and brain stimulant drug abuse and alcoholism History of severe liver failure History of seizures History of Anxiety Disorders Cardiac or respiratory recurrence in the first 6 days of hospitalization

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **314**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups of drugs and placebo. Randomization by block randomization method in 4.6.8 blocks and using random numbers taken from the site <https://www.sealedenvelope.com>. A person who examines patients for inclusion is unaware of the random patient allocation table. Information about each patient is collected from the time of the examination in terms of enrollment conditions until each of the following outcomes is reached: The end of the follow-up period or death or withdrawal from the study, whichever occurs sooner, will be recorded and reported.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the person measuring and determining the outcomes do not know which group of drugs or placebos the patient is in. In order not to inform patients, physicians, nurses and the entire treatment team about assigning patients to two groups, placebos are prepared with the help of the pharmacosynthetic department of the School of Pharmacy in a completely similar way in terms of color, size and weight. People in the drug group are given 200 mg of oral modafinil (Torrent Pharma, UK) daily, dissolved in 10 cc of plain water, at 9 a.m. through a tube in the stomach for one week. . Patients' GCS (Glasgow Coma Score) score is recorded every 8 hours. (The highest GCS score is recorded within 8 hours.)

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2021-01-06, 1399/10/17

Ethics committee reference number

IR.SUMS.MED.REC.1399.502

Health conditions studied

1

Description of health condition studied

Brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

Unawareness condition

Timepoint

At intervals of one, three and six months after discharge from the hospital

Method of measurement

GOS-E (Glasgow Outcome Scale-Extended)

Secondary outcomes

1

Description

Agitation

Timepoint

Every 4 hour

Method of measurement

RASS (Richmond Agitation-Sedation Scale)

2

Description

Level of Conciseness

Timepoint

Every 8 hours

Method of measurement

GCS(Glasgow Coma Score)

Intervention groups

1

Description

Intervention group: Patients in the drug group receive 200 mg of oral modafinil daily (Torrent Pharma, UK) dissolved in 10 cc of plain water at 9 am through a tube placed in the stomach

Category

Treatment - Drugs

2

Description

Control group: In order not to inform patients, physicians, nurses and the entire treatment team about assigning patients to two groups, placebo is prepared with the help of the pharmacosynthetic department of the School of

Pharmacy in a completely similar way in terms of color, size and weight. The placebo is dissolved in 10 cc of plain water and patients receive the placebo at 9 am through a tube inserted into the stomach.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajae hospital

Full name of responsible person

Zahra Zand

Street address

Rajaei Hospital, Shahid Chamran Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbass Rezaiean Zadeh

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Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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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

Shiraz 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

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Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Zand
Position
Extern
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is against the policies of our center.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available