Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Rajaee 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)

Phone

+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 Rajaee 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 Rajaee 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
Rajaee hospital
Full name of responsible person
Zahra Zand
Street address
Rajaei Hospital, Shahid Chamran Boulevard
City
Shiraz
Province
Fars
Postal code
7194815711
Phone
+98 71 3636 4001
Email
rajaeehospital@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Abbass Rezaiean Zadeh
Street address
Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3647 4270
Email
masihifarzaneh@yahoo.com
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

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

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

zandfarid@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farid Zand

Position

Intensivist

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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zandfarid@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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7134844119

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masihifarzaneh@yahoo.com

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