

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of Modafinil on consciousness in patients with brain damage in Intensive care unit

Protocol summary

Study aim

Evaluation of the effect of Modafinil on consciousness in patients with brain damage in Intensive care unit

Design

A double-blind clinical trial study, 126 patients were randomly divided into 2 groups. The groups are in parallel. The trial phase is 3.

Settings and conduct

Patients diagnosed with delirium in Valiasr hospital in Arak city are divided into 2 groups by simple randomization using block method. The study is double-blind. In this study, the supervisor knows about the grouping and prescribes the drugs for the patients, and the interns do not know about the prescribed drugs, and the follow-up of the patients is with the interns, and the analyst does not know about the grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: GCS less than 10, being intubated, age between 16 and 50 years, history of brain injury, absence of space-occupying lesion in brain CT scan (hematoma, tumor), absence of seizure history No addiction to psychoactive substances and narcotics, no history of amphetamine use, no history of hypertension, ischemic heart disease and diabetes mellitus, heart rate less than 120 times per minute Exclusion criteria: arrhythmia, evidence of drug sensitivity, death, patient's lack of consent to participate in the study

Intervention groups

Intervention group: Modafinil drug will be administered orally or by gavage in the amount of 100 mg twice a day. Control group: will receive placebo twice a day.

Main outcome variables

Time required until ventilator isolation, patients' GCS score, patients' agitation intensity, average mortality, duration of hospitalization in the ICU unit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N190**

Registration date: **2023-10-12, 1402/07/20**

Registration timing: **prospective**

Last update: **2023-10-12, 1402/07/20**

Update count: **0**

Registration date

2023-10-12, 1402/07/20

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Modafinil on consciousness in patients with brain damage in Intensive care unit

Public title

Evaluation of the effect of Modafinil on consciousness in patients with brain damage in Intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

GCS less than 10 Intubation Between 16 and 50 years
History of brain injury Absence of space-occupying lesion in brain CT scan (hematoma, tumor) No history of seizures No addiction to psychoactive substances and narcotics No history of hypertension, ischemic heart disease and diabetes mellitus Heart rate less than 120 beats per minute

Exclusion criteria:

arrhythmia Emergence of evidence of drug sensitivity
Death Lack of consent of the patient to participate in the study

Age

From **16 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the supervisor knows about the grouping and prescribes the drugs for the patients, and the interns do not know about the prescribed drugs, and the follow-up of the patients is with the interns, and the analyst does not know about the grouping, and as a result, the study will be double-blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2023-03-05, 1401/12/14

Ethics committee reference number

IR.ARAKMU.REC.1401.343

Health conditions studied

1

Description of health condition studied

Brain damage

ICD-10 code

P11.1

ICD-10 code description

Other specified brain damage due to birth injury

Primary outcomes

1

Description

Time required until ventilator isolation

Timepoint

End of study

Method of measurement

Clinical observation

2

Description

level of consciousness

Timepoint

On consecutive days from the first day of hospitalization to the day of discharge

Method of measurement

Glasgow coma scale

3

Description

Agitation intensity

Timepoint

On consecutive days from the first day of hospitalization to the day of discharge from the intensive care unit

Method of measurement

Richmond Agitation Sedation Score

4

Description

Mortality

Timepoint

End of study

Method of measurement

Clinical observation

5

Description

The number of days of hospitalization in the intensive care unit

Timepoint

End of study

Method of measurement

Clinical observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Modafinil drug will be administered orally or by gavage in the amount of 100 mg twice a day.

Category

Treatment - Drugs

2

Description

Control group: will receive placebo twice a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr Behnam Mahmodie

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

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

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