Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 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)

Phone
+98 86 3222 2003

Email address
f.farokhi@arakmu.ac.ir

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 comittee of Arak University of Medical Sciences
Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,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 squre, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
mahmodie@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Davoud Hekmatpou
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
hekmatpou@arakmu.ac.ir
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
Other areas of specialty/work
Anesthesiology
Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street
City
Arak
Province
Markazi

Postal code
3814957558
Phone
+98 86 3222 2003
Email
modir.he@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Behnam Mahmodie
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
mahmodie@arakmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Nilofar Khademi
Position
medicine student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
leukocyte98@gmail.com

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