Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of oral caffeine in helping to liberate (Liberation) from the ventilator in intubated and mechanically ventilated patients admitted to the intensive care unit

Protocol summary

Study aim

Evaluation of the effect of oral caffeine in helping to liberate from the ventilator in intubated and mechanically ventilated patients admitted to the intensive care unit

Design

Clinical trial with control group, with parallel groups, double-blind, randomized with the help of Excel statistical software, phase 3 on 124 patients

Settings and conduct

This study is performed in Imam Hossein Hospital, Tehran, Iran. Patients admitted to the General ICU who, according to the Intensive Care Specialist, is more than 48 hours dependent on a ventilator will be randomly divided into two groups. In the intervention group, caffeine tablets with a dose of 200 mg twice daily through the gastric tube, and in the control group, the corresponding placebo is received with the same dose. After recording the cause of hospitalization and APACHE score, patients are visited daily in terms of the possibility of separation from the device, and in case of appropriate clinical conditions, the device mode is changed to spontaneous and RSBI is calculated and weaning decision is made based on it. The duration of the need for mechanical ventilation, the need for re-intubation, the duration of hospitalization in the ICU, and the duration of hospitalization will be recorded. The drug and placebo are also labeled in packages and the patient and caregiver are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all intubated patients in the General ICU who are expected to be ventilators for more than 48 hours. Exclusion criteria: myopathy, ischemic heart problems, and cardiac arrhythmias, neurosurgery patients, caffeine sensitivity.

Intervention groups

In the intervention group, caffeine tablets with a dose of 200 mg twice daily through the gastric tube and in the control group, the corresponding placebo is received with the same dose.

Main outcome variables

Duration of mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210110049990N2**
Registration date: **2021-12-23, 1400/10/02**
Registration timing: **prospective**

Last update: **2021-12-23, 1400/10/02**
Update count: **0**

Registration date

2021-12-23, 1400/10/02

Registrant information

Name

seyedpouzhia shojaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 0000

Email address

p.shojaei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of oral caffeine in helping to liberate (Liberation) from the ventilator in intubated and mechanically ventilated patients admitted to the intensive care unit

Public title
Evaluation of the effect of caffeine on separation from ventilators of patients admitted to the intensive care unit
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All intubated patients in the General ICU are expected to be ventilator-dependent for more than 48 hours.
Exclusion criteria:
Myopathy Ischemic heart problems Cardiac arrhythmia Neurosurgery patients Caffeine sensitivity
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **124**
Randomization (investigator's opinion)
Randomized
Randomization description
With simple randomization and using a random number table and individual randomization unit. To randomize, we use a table consisting of random digits 0 to 9. Each digit of this table is repeated the same on average. There is no pattern of recognizable numbers. In this method, each number is assigned to a treatment group. We start from the first line of the table and move down line by line. For the two treatments, we put the numbers 0 to 4 for treatment A and the numbers 5 to 9 for treatment B. The numbers in the first line of the table are as follows: 0,5,2,7,8,4,3,7,4,1,6,8,3,8,5,1,5,6,9,6, ... Now for people based on the above numbers, we have the following allocation: A, B, A, B, B,. We will continue the above process until the two groups are completed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this two-way blind study, the hub group is assigned by the physician using statistical software and the drug and placebo are provided to the clinical caregiver in a labeled form. In order to prevent any problems, information about the drugs is provided only to the principal investigator.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University
Street address
Yemen Street, Shahid Chamran Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2021-10-31, 1400/08/09
Ethics committee reference number
IR.SBMU.RETECH.REC.1400.515

Health conditions studied

1

Description of health condition studied
Intubated and mechanically ventilated patients admitted to the intensive care unit
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
APACHEII
Timepoint
The beginning of the study and 7 days later
Method of measurement
APACHEII form and laboratory information

2

Description
Rapid Shallow Breathing Index
Timepoint
The beginning of the study and 7 days later
Method of measurement
Respiratory rate divided by respiratory volume

Secondary outcomes

1

Description
Duration of mechanical ventilation
Timepoint
The beginning of the study and 7 days later
Method of measurement
Review of the patient's clinical record

Intervention groups

1

Description
Intervention group: Patients receive caffeine tablets at a dose of 200 mg twice daily through the gastric tube.
Category
Treatment - Drugs

2

Description
Control group: Patients receive a placebo at a dose of 200 mg twice daily through a gastric tube.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Seyed Poujea Shojaei
Street address
Shahid Madani St.
City
Tehran
Province
Tehran
Postal code
1476716165
Phone
+98 21 7343 2000
Email
P.Shojaei@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Arabi Street, Daneshjoo Boulevard, Velenjak
City
Tehran
Province
Tehran
Postal code
1476716165
Phone
+98 21 7343 3000
Email
zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Poujea Shojaei
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Madani Street
City
Tehran
Province
Tehran
Postal code
1476716165
Phone
+98 21 7343 2000
Email
P.Shojaei@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyed Poujea Shojaei
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Madani Street
City
Tehran
Province
Tehran
Postal code
1476716165
Phone
+98 21 7343 2000
Email
P.Shojaei@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Poujea Shojaei
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Madani Street
City
Tehran
Province
Tehran
Postal code
1476716165
Phone
+98 21 7343 2000
Email
P.Shojaei@sbmu.ac.ir

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
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