

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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

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