

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of effects of oral medroxyprogesterone and donepezil in improvement of respiratory status and facilitation in weaning of mechanical ventilation in patients undergoing mechanical ventilation in ICUs of Shahid Dr. Rahnemoon Yazd

Protocol summary

intensive care unit and hospital, clinical status of patients, hospital discharge, scorpion sofa and GCS.

Study aim

Determination and comparison of the effects of oral medroxyprogesterone and oral donepezil on improving respiratory status and facilitating mechanical ventilation discontinuation in patients undergoing mechanical ventilation in intensive care units

Design

Patients will be randomly divided into 3 groups receiving 10 mg daily Donepezil or MP or placebo randomly divided by permissive block method and will use their own medicine once a day for 10 days. Therefore, demographic and clinical data of registered patients, as well as medication history, clinical profiles, GCS and Sophia Score are reported.

Settings and conduct

Intensive care units of Dr. Rahnemoon Hospital of Yazd

Participants/Inclusion and exclusion criteria

Mechanical ventilation through endotracheal tube for at least 24 hours, oxygen saturation greater than 90%, FIO₂ less than 50% and PEEP less than 8 cm water, hemodynamic stability over the past 12 hours, sedation withdrawal or sedation reduction Over the past 48 hours, neurological status stability with Ramsay's score was less than 5 and body temperature between 36 and 39 degrees. Exclusion criteria would be pregnancy or lactation, under 18 years of age, known allergy to donepezil or medroxyprogesterone, tracheostomy, Any hemodynamic instability, need to be obtained Sedation or unconsciousness, concurrent administration of potentially breathing stimulants such as doxapram and medroxyprogesterone, hypothyroidism

Intervention groups

One group is the Medroxy Progesterone recipient, the other is Donepezil and the last is the placebo recipient.

Main outcome variables

Mortality rate, duration of ventilation, length of stay in

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190810044500N2**

Registration date: **2020-04-01, 1399/01/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-01, 1399/01/13**

Update count: **0**

Registration date

2020-04-01, 1399/01/13

Registrant information

Name

Fatemeh Saghafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3419

Email address

f.saghafi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-21, 1398/09/30

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of effects of oral medroxyprogesterone and donepezil in improvement of respiratory status and facilitation in weaning of mechanical ventilation in patients undergoing mechanical ventilation in ICUs of Shahid Dr. Rahnemoon Yazd

Public title
Evaluation of effects of oral medroxyprogesterone and donepezil in improvement of respiratory status and facilitation in weaning of mechanical ventilation in patients undergoing mechanical ventilation in ICUs

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Mechanical ventilation through endotracheal tube for at least 24 hours oxygen saturation greater than 90% FIO2 less than 50% PEEP less than 8 cm water hemodynamic stability over the past 12 hours sedation withdrawal or sedation reduction Over the past 48 hours neurological status stabilized with Ramsay's score less than 5 temperature between 36 and 39 degrees
Exclusion criteria:
Pregnancy or lactation under 18 years of age tracheostomy hepatic encephalopathy cerebral edema acute hydrocephalus myasthenia gravis Acute polyneuropathy lack of decision to discontinue respiratory support prolonged cardiac arrest with poor neurologic prognosis coincident extubation with day one acute right ventricular failure renal failure plasma urea exceeding (25 mol / L), Plasma creatinine greater than (180 mol / min) or creatinine clearance less than 30 ml / min, or more than 25% increase in creatinine over the past 24 hours contrast injection over the past six hours Serum sodium level greater than (150 m Eq) / L serum potassium level less than 3.5 (m Eq) / L metabolic alkalosis with arterial pH greater than 7.5 need for sedation or unconsciousness concurrent administration of drugs Potential respiratory stimulants such as doxapram and medroxyprogesterone hypothyroidism Known allergy to donepezil or medroxy progesterone

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description
The three drugs Donepezil and Medroxyprogesterone and placebo were named in letters A, B and C. The order of prescribing of medications to the specimens was determined using a random number table

Blinding (investigator's opinion)
Triple blinded

Blinding description
Blindness was performed on clinical caregivers, including physicians and nurses, as well as variables assessors and data analysts.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

faculty of ethics of medical sciences - shahid sadoughi university of medical sciences

Street address

Gomnam shohada boulevard - shahid sadoughi university of medical sciences

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2019-11-11, 1398/08/20

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.198

Health conditions studied

1

Description of health condition studied

weaning of mechanical ventilation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

blood gas includes PO2, PCO2, PHCO3, O2 saturation and PH

Timepoint

Before intervention and one day after and after weaning

of mechanical ventilation
Method of measurement
blood sample

2

Description

hemoglobin

Timepoint

Before intervention and one day after and after weaning of mechanical ventilation

Method of measurement

blood sample

3

Description

level of consciousness

Timepoint

Before intervention and one day after and after weaning of mechanical ventilation

Method of measurement

glass coma scale

4

Description

sofa score

Timepoint

Before intervention and one day after and after weaning of mechanical ventilation

Method of measurement

Scoring based on pulmonary, coagulation, hepatic, cardiovascular, central nervous system and renal status

Secondary outcomes

1

Description

duration of weaning

Timepoint

From the process of separation from the device to the patient's spontaneous breathing

Method of measurement

Counting the number of days

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

2

Description

Control group:

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dr. Rahneemoon hospital Yazd

Full name of responsible person

Mohamad Hosein Dehghani

Street address

Farokhi street

City

Yazd

Province

Yazd

Postal code

۸۹۱۵۱۷۳۱۴۹

Phone

+98 35 3626 0001

Email

Rahneemoonhospital@ssu.ac.ir

Web page address

<https://web.ssu.ac.ir/index.aspx?lang=1&sub=4>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mohamad Reza Mirjalili

Street address

Bahonar Square

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3724 1171

Fax

+98 35 3724 0371

Email

ravabet@SSU.AC.IR

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

+98 35 3820 3419

Fax
Email
F.saghafi@ssu.ac.ir

Person responsible for general inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh Saghafi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Professor Hesabi Blvd., Yazd Province, Yazd, Iran
City
Yazd
Province
Yazd
Postal code
۸۹۱۵۱۷۳۱۴۹
Phone
+98 35 3820 3419
Fax
Email
F.saghafi@ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh Saghafi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Professor Hesabi Blvd., Yazd Province, Yazd, Iran
City
Yazd
Province
Yazd
Postal code
۸۹۱۵۱۷۳۱۴۹
Phone

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh Saghafi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Professor Hesabi Blvd., Yazd Province, Yazd, Iran
City
Yazd
Province
Yazd
Postal code
۸۹۱۵۱۷۳۱۴۹
Phone
+98 35 3820 3419
Fax
Email
F.saghafi@ssu.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

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