Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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 Denepezil 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 intensive care unit and hospital, clinicalstatus of patients, hospital discharge, scorpion sofa and GCS.

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

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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. Rahnemoon hospital Yazd
Full name of responsible person
Mohamad Hosein Dehghani
Street address
Farokhi street
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Yazd
Province
Yazd
Postal code
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Rahnemoonhospital@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
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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

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

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Professor Hesabi Blvd., Yazd Province, Yazd, Iran

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Person responsible for scientific inquiries

Contact

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Position

Associate professor

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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