Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Sep 2026

The effect of surfactant on clinical outcome of patients with COVID-19 under mechanical ventilation

Protocol summary

Study aim
Assessing the effect of surfactant on clinical outcome in patients with Covid-19 under mechanical ventilation
Design
Two arm parallel group randomized trial with blinded care and outcome assessment
Settings and conduct
COVID-19 patients under mechanical ventilation would enter the study; one group would receive the standard treatment added with placebo and the other group would receive standard care plus intra-tracheal surfactant
Participants/Inclusion and exclusion criteria
Inclusion criteria: If the patient is intubated and under mechanical ventilation with SpO2<85% If the patient has confirmed COVID-19 Exclusion criteria: Existence of a major underlying pulmonary disease in addition to COVID-19 Underlying congenital heart disease
Intervention groups
In the intervention group, based on the dose announced in the study protocol, surfactant is prescribed inside the trachea in two doses at a distance of 6 hours, and at the same time, the dependent variables of the study are measured. At the same time, in the control group, the same volume of normal saline is administered in the trachea within the same time schedule
Main outcome variables
patient mortality; ICU length of stay; Time to be under mechanical ventilation

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20091201002804N12**
Registration date: **2020-06-01, 1399/03/12**
Registration timing: **registered_while_recruiting**
Last update: **2020-06-01, 1399/03/12**
Update count: **0**
Registration date
2020-06-01, 1399/03/12

Registrant information
Name
Ali Dabbagh
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-04-20, 1399/02/01
Expected recruitment end date
2020-06-21, 1399/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of surfactant on clinical outcome of patients with COVID-19 under mechanical ventilation

Public title
The effect of surfactant on clinical outcome of patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

if the patient is intubated and under mechanical ventilation with SpO2<85% If the patient has confirmed COVID-19

Exclusion criteria:

Coexisting underlying pulmonary disease except for COVID-19 Underlying congenital hear disease

Age

From **18 years** old to **99 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After the participant enters the study, i.e. after the qualification of the patients in the trial is confirmed and their informed written consent is taken, simple randomization will be done as follows: 1- Table of random numbers will be used for creation of coincidence of random allocation. 2- In order to hide the random allocation process, the central randomization approach will be used, while the random sequence would be at the disposal of one of the researchers except for the principal investigator.

Blinding (investigator's opinion)

Triple blinded

Blinding description

participants after entering the study would not know whether they are in the drug or placebo group healthcare providers (Physicians and nurses) would administer the prepared vial including drug or placebo while they do not know its content; the vial would be assimilated; regardless of drug or placebo principle investigator does not know whether the patient belongs to the drug group or the placebo group since the patients have been randomized

Placebo

Not used

Assignment

Factorial

Other design features

COVID-19 treatment study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Deputy for Research and Technology, Shahid Beheshti University of Medical Sciences, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-03-28, 1399/01/09

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.016

Health conditions studied

1

Description of health condition studied

Mortality of Patients from COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

time for mechanical ventilation

Timepoint

throughout the study, the time that patient has stayed under mechanical ventilation

Method of measurement

clinical records

Secondary outcomes

1

Description

ICU mortality rate

Timepoint

throughout the study in the ICU ward

Method of measurement

clinical records

Intervention groups

1

Description

Intervention group: Intra-tracheal surfactant in COVID-19 patients who are under mechanical ventilation, which includes the administration of a standard dose of surfactant inside the airway of the patient with COVID-19 diagnosis, which is administered immediately on the first day of intubation and in two doses at intervals within 6 hours. The dose of the drug is a vial containing 4 ml,

equivalent to 100 mg, which is prescribed for an adult weighing about 70 kg each time, and if the patient's weight is higher, it will be adjusted accordingly. The drug is from the brand Beraksurf® and is supplied by Tekzima.

Category

Treatment - Drugs

2

Description

Control group: all the treatment protocols including standard of care is the same as the treatment group; except for the intrathecal administration of surfactant. An equivalent volume of normal saline is used as placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres hospital

Full name of responsible person

Ali Dabbagh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Velenjak, Chamran Exp Way

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Tehran

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Grant name

Grant code / Reference number

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

No

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

Ali Dabbagh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
all collected deidentified IPD
When the data will become available and for how long
starting in January 2022
To whom data/document is available
the data would be available for people working in academic institutions and people working in businesses
Under which criteria data/document could be used
by formal permission form PI
From where data/document is obtainable
Address of the Principal Investigator
What processes are involved for a request to access data/document
Formal application confirmed by the institution
Comments