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

More options

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
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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

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Province
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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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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	

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