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)

Phone
+98 21 2243 2572

Email address
alidabbagh@sbmu.ac.ir

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 heart 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
2. **Timepoint**
   throughout the study in the ICU ward
3. **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 |
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.
| 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 |

Afshin Zarghi

**Street address**
Velenjak, Chamran Exp Way

**City**
Tehran

**Province**
Tehran

**Postal code**
1983535511

**Phone**
+98 21 2387 2202

**Fax**
+98 21 2387 2202

**Email**
info@sbmu.ac.ir
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

Street address
Sa'adat Abad

City
Tehran

Province
Tehran

Postal code
1998738341

Phone
+98 21 2387 2202

Email
alidabbagh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Ali Dabbagh

Position
Professor
Person responsible for updating data

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

Street address
Sa'adat Abad

City
Tehran

Province
Tehran

Postal code
1998738341

Phone
+98 21 2207 4101

Email
alidabbagh@yahoo.com
### Sharing plan

| Data Type                                      | Availability                    |
|-----------------------------------------------|----------------------------------|
| 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

Email: alidabbagh@yahoo.com
