

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 SpO<sub>2</sub><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 SpO<sub>2</sub><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

**Street address**

Sa'adat Abad

**City**

Tehran

**Province**

Tehran

**Postal code**

1998738341

**Phone**

+98 21 2207 4100

**Fax**

+98 21 2207 4101

**Email**

alidabbagh@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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

**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

**Street address**

Sa'adat Abad

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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****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**

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Tehran

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**Postal code**

1998738341

**Phone**