

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Efficacy evaluation of FLUVAR® in the onset of the disease with symptoms of respiratory infection synonymous with the symptoms of COVID-19 in patients referred to emergency departments and clinics

#### Protocol summary

##### Study aim

Determining the effect of FLUVAR® nebulizer on increasing blood oxygen saturation and reducing dyspnea in COVID-19 patients

##### Design

Phase 2 of two-stage multicenter clinical trial, first stage on 30 COVID19 patients admitted to emergency department in 2 randomized groups of drug and placebo. After interim analysis, if the results were significant, second phase was performed on 60 COVID19 patients admitted to ICU in 2 groups of randomized drug and control without blinding. Randomization: In first stage by assigning random codes to drugs and placebo and in second stage by receiving or not receiving FLUVAR® by volunteers intermittently

##### Settings and conduct

First stage on patients admitted to emergency department and second stage on patients admitted to ICU of 3 hospitals in Isfahan. Blinding approach: In first stage, for volunteer, researcher, prescriber of drug and data analyzer

##### Participants/Inclusion and exclusion criteria

First stage: Inclusion criteria: 18 years and older, emergency hospitalization for COVID19, signing informed consent, O2sat 94% or less (without oxygen delivery) or respiratory rate of 35 or more Exclusion criteria: history of moderate or severe asthma, participating in another trial for COVID19, unstable vital conditions Second stage: Inclusion criteria: age 18 and older, ICU admission, signing informed consent, confirmation of COVID19 by PCR or CT-scan, O2sat 94% or less (with oxygen delivery) Exclusion criteria: as above

##### Intervention groups

First stage: Medication: Treatment based on protocol + single dose of 5ml FLUVAR® nebulizer Placebo: Treatment based on protocol + single dose of 5ml normal saline nebulizer Second stage: Medication:

Treatment based on protocol + 5ml of FLUVAR® nebulizer, twice a day, up to 2 weeks Control: Treatment based on protocol

##### Main outcome variables

1. Change in O2sat 2. Dyspnea score with Visual Analogue Scale 3. Adverse drug effects

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200404046932N1**

Registration date: **2021-10-14, 1400/07/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-14, 1400/07/22**

Update count: **0**

##### Registration date

2021-10-14, 1400/07/22

##### Registrant information

##### Name

Leila Safaeian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7087

##### Email address

leila\_safaeian@pharm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2021-12-22, 1400/10/01

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Efficacy evaluation of FLUVAR® in the onset of the disease with symptoms of respiratory infection synonymous with the symptoms of COVID-19 in patients referred to emergency departments and clinics

**Public title**  
Therapeutic effect of FLUVAR® for COVID-19

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age 18 years and older  
Signing informed consent  
Possessing two distinct respiratory signs of COVID-19  
O2Sat below 94% or positive signs on CT scan or positive PCR result for COVID-19  
**Exclusion criteria:**  
History of moderate or severe respiratory asthma  
Participating in another clinical trial for COVID-19

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Similar medicine containers are used for medicine and placebo. After filling the vials with medication and placebo, random codes are assigned to them using a random number table.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
The researcher is unaware of which medication or placebo is being delivered / The medication and placebo formulator is unaware of the recipients / The prescriber of the medication and placebo is unaware of the grouping and content of the containers / The volunteers are unaware of the contents of their medication containers /The collector of outcomes and the analyst are unaware of the groups.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**  
The study has two stages. The first step is done with two parallel groups of medication and placebo. After interim analysis, if drug efficacy is confirmed, the study is continued without placebo group and the results of medication group are compared with control group without receiving FLOVAR®. All groups receive standard care and treatment.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

##### Street address

Ethics Committee of Isfahan University of Medical Sciences, Hezarjarib Blvd, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

#### Approval date

2020-05-12, 1399/02/23

#### Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.085

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19 disease

## Primary outcomes

### 1

#### Description

O2sat difference one hour post intervention

#### Timepoint

One hour after the intervention

#### Method of measurement

Pulse oximeter instrument

## Secondary outcomes

## 1

### **Description**

Dyspnea scale

### **Timepoint**

One hour after the intervention

### **Method of measurement**

By Visual Analogue Scale questionnaire (VAS)

## 2

### **Description**

Intervention side effects

### **Timepoint**

From the beginning to one day after the end of the intervention

### **Method of measurement**

Observation and interview questionnaire

## **Intervention groups**

## 1

### **Description**

Intervention group 1- First intervention stage: Care and treatment based on standard protocol + Receiving single dose (5 ml) of FLUVAR® using a Pari Master nebulizer connected to the patient's oxygen uptake pathway

### **Category**

Treatment - Drugs

## 2

### **Description**

Intervention group 2- First intervention stage: Care and treatment based on standard protocol + Receiving single dose (5 ml) of normal saline using a Pari Master nebulizer connected to the patient's oxygen uptake pathway

### **Category**

Treatment - Drugs

## 3

### **Description**

Intervention group 3- Second intervention stage: Care and treatment based on standard protocol + Receiving FLUVAR® using a Pari Master nebulizer connected to the patient's oxygen uptake pathway, 5ml every dose, two times a day, up to 2 weeks

### **Category**

Treatment - Drugs

## 4

### **Description**

Control group- Second intervention stage: Care and treatment based on standard protocol

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Amin Hospital Emergency Department, Gharazi Hospital Emergency Department, Khorshid Hospital Emerge

#### **Full name of responsible person**

Leila Safaeian

#### **Street address**

Pharmacology Department, Isfahan University of Medical Sciences, Isfahan, Iran ,

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

81746-73461

#### **Phone**

+98 31 3667 1780

#### **Email**

leila\_safaeian@pharm.mui.ac.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Hakiman e Shargh Research Co.

#### **Full name of responsible person**

Sayyed Ali Alavi

#### **Street address**

Technology Park, Isfahan Science & Technology Town

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

8415683111

#### **Phone**

+98 31 3667 1780

#### **Email**

sayyediallavi@gmail.com

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Hakiman e Shargh Research Co.

### **Proportion provided by this source**

100

### **Public or private sector**

Private

### **Domestic or foreign origin**

Domestic

### **Category of foreign source of funding**

empty

### **Country of origin**

### **Type of organization providing the funding**

Industry

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Hakiman e Shargh Research Co.

**Full name of responsible person**

Sayyed Ali Alavi

**Position**

Managing Director

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Technology Park, Isfahan Science & Technology Town,  
Isfahan, Iran

**City**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Protection of patients' confidential medical information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The study protocol is provided after designing and  
loading the drug website.

**When the data will become available and for how long**

For 6 months from the time the data is uploaded to the  
drug site

**To whom data/document is available**

Applicants after applying through the site and receiving  
the approval of the executor

**Under which criteria data/document could be used**

For scientific purposes only

**From where data/document is obtainable**

Website of the medicine

**What processes are involved for a request to access data/document**

Identity registration - Verification of identity -  
Registration of application

**Comments**