

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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

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

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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

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8415683111

Phone

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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

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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