Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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
Isfehan

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 ,
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Isfehan
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81746-73461
Phone
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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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Postal code
8415683111
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sayyedalialavi@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

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

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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