

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the effect of FLUVAR® in respiratory dosage form on the prevention of COVID-19 respiratory infection

Protocol summary

Study aim

Evaluation of safety and efficacy of FLUVAR® in prevention of COVID-19 compared to COLDAMARIS® and the control group in healthy population

Design

Phase 3, three parallel arms, double blinded, non-randomized, clinical trial on 1000 healthy volunteers

Settings and conduct

On the healthy volunteers at risk of COVID-19 Blinding: The researcher is unaware of which drug or placebo is being delivered / The drugs formulator is unaware of the recipients / The prescriber of the drugs is unaware of the grouping and content of the containers /The collector of outcomes and the analyst are unaware of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 years and older- Signing informed consent Exclusion criteria: History of moderate or acute respiratory asthma- Participating in another clinical trial for COVID-19

Intervention groups

FLUVAR® nasal spray group 500µl once a week
COLDAMARIS® group 500 µl once a week Drug-free control group

Main outcome variables

Rate of COVID-19 infection (Time Frame: 14-20 months)
Acquisition of COVID-19 infection as confirmed by positive PCR swab taken 3-5 days after symptom onset

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200404046932N2**
Registration date: **2021-10-30, 1400/08/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-30, 1400/08/08**

Update count: **0**

Registration date

2021-10-30, 1400/08/08

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

2020-04-20, 1399/02/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of FLUVAR® in respiratory dosage form on the prevention of COVID-19 respiratory infection

Public title

Preventive effect of FLUVAR® on COVID-19

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years and older Informed consent

Exclusion criteria:

History of moderate or severe asthma Participating in another clinical trial for COVID-19

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **1000**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

The researcher is unaware of which drug is delivered to which volunteer. The formulator of the two drugs is unaware of the recipients of the drugs and the dispenser of the drugs is unaware of the grouping and content of the drugs. The collector of results and the analyzer of data are also unaware of the type of drug groups.

Placebo

Not used

Assignment

Parallel

Other design features**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

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Province

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Postal code

81746-73461

Approval date

2020-04-05, 1399/01/17

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.014

Health conditions studied**1****Description of health condition studied**

COVID-19 Prophylaxis

ICD-10 code

U07.2

ICD-10 code description

COVID-19, virus not identified

Primary outcomes**1****Description**

Rate of COVID-19 infection

Timepoint

Time Frame: 14-20 months after admission to the study

Method of measurement

Acquisition of COVID-19 infection as confirmed by positive PCR swab taken 3-5 days after symptom onset

Secondary outcomes**1****Description**

Duration and intensity of COVID-19 symptoms of infected participants

Timepoint

Two weeks after onset of disease symptoms

Method of measurement

Questionnaire of symptoms, duration and intensity of disease

2**Description**

Side effects of intervention

Timepoint

Duration of Study

Method of measurement

Questionnaire of side effects

Intervention groups**1****Description**

Intervention group 1: Three puffs of FLOVAR® spray on each side, equivalent to a total of 500µl of medicine, once a week and receiving an additional dose of medicine in case of contact with a person suspected of having Covid 19 or disease carrier

Category

Prevention

2**Description**

Intervention group 2: Three puffs of COLDAMARIS®

spray on each side, equivalent to a total of 500µl of medicine, once a week and receiving an additional dose of medicine in case of contact with a person suspected of having Covid 19 or disease carrier

Category

Prevention

3**Description**

Control group: Without medicine

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hospitals of Isfahan University of Medical Sciences

Full name of responsible person

Leila Safaeian

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2**Recruitment center****Name of recruitment center**

Sheikh bahaei Technology Park, Isfahan Science & Technology Town

Full name of responsible person

Hamid Mahdavi

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

Hakiman e Shargh Research Co.

Full name of responsible person

Sayyed Ali Alavi

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Technology Park, Isfahan Science & Technology Town

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sayyedialavi@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**

Esfahan University of Medical Sciences

Full name of responsible person

Leila Safaeian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific 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 updating data

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Full name of responsible person

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Managing Director

Latest degree

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Other areas of specialty/work

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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 participants' 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

No - There is not 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 - Non-commercial

From where data/document is obtainable

Drug website

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

Registration - Registration of application - Verification of identity - Receipt of approval of the executor

Comments