Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 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

City
Isfahan

Province
Isfehan

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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8415683111

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hmahdavi@istt.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

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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
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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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