

# 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

**City**

Isfahan

**Province**

Isfahan

**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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Isfahan University of Medical Sciences, Hezarjarib BLVD

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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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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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**Province**

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**Phone**

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**Email**

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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Technology Park, Isfahan Science & Technology Town,  
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## Person responsible for updating data

### 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**

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**Email**

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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**