

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Evaluation of safety and antiviral effect of Sakarya-20 inhaled solution containing fuzzy nanoparticles on the recovery of patients with Covid-19

#### Protocol summary

##### Study aim

Determination of safety and efficacy of Sakarya-20 inhalation solution as antiviral therapy in COVID-19 patients

##### Design

This study is a pilot single assignment clinical trial and add-on design study, in which patients receive Sakarya-20 inhalation solution in addition to standard treatment. The patients who refer to the emergency department of Azad University hospitals due to COVID-19 disease were evaluated by a physician in terms of inclusion and non-inclusion criteria and after completing the consent form Letters (by the patient, guardian or guardian) are randomized using the random number method and entered into the project in a treated or controlled grouping.

##### Settings and conduct

The trial is performed in Farhikhtegan Hospital of Azad University based on open single assignment pilot clinical trial. This study is open labeled clinical trial (there is no need for blindness and randomization).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age above 18 years, Having a number of clinical signs of coronary heart disease by a specialist, Confirmation of the disease by diagnostic test PCR-viral load test. Inclusion criteria: Age under 18, need to be hospitalized, Consumption of any other pharyngeal inhaler, pregnancy and lactation

##### Intervention groups

Ten patients were enrolled in the study and all patients take Sakarya-20 pharyngeal inhalation solution along with standard treatments. The method of administration is that the patient first inhales 0.5 cc every 8 hours for two days, and from the third to the ninth day 0.5 cc solution once a day.

##### Main outcome variables

Virus clearance

#### General information

##### Reason for update

Increase the number of patients from 10 to 14, according to the judges

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211003052661N1**

Registration date: **2021-10-14, 1400/07/22**

Registration timing: **prospective**

Last update: **2022-03-07, 1400/12/16**

Update count: **1**

##### Registration date

2021-10-14, 1400/07/22

##### Registrant information

##### Name

amir hoseyn moghtader mozhdehi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3253 4518

##### Email address

amirtxt@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-28, 1400/12/09

##### Expected recruitment end date

2022-04-29, 1401/02/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of safety and antiviral effect of Sakarya-20 inhaled solution containing fuzzy nanoparticles on the recovery of patients with Covid-19

## Public title

Evaluation of the effect of Sakarya-20 in the treatment of Covid disease - 19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Admission of Covid-19 patients over 18 years of age who are diagnosed based on a number of clinical coronary symptoms (dry cough, fever, headache, sore throat, lymphopenia or thrombocytopenia) by a physician and confirmed by PCR-viral diagnostic test load test (swallowing of the throat and nose) is performed in the laboratory. COVID-19 patients with mild to moderate disease who do not need to be admitted to the coronary ward (no lung involvement or very little involvement confirmed by CT scan) are included in the study if they are satisfied.

### Exclusion criteria:

Age under 18, Lung involvement (need to be hospitalized), malignant tumor and other acute systemic diseases, co-infection with HIV, tuberculosis, history of asthma, asthma-like attacks and respiratory problems, life-threatening comorbidity Consumption of any other pharyngeal inhaler, pregnancy and lactation

## Age

From **18 years** old

## Gender

Both

## Phase

0

## Groups that have been masked

*No information*

## Sample size

Target sample size: **14**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Research Ethics Committee of the Faculty of Pharmacy and Pharmaceutical Sciences, Tehran Azad Univer

#### Street address

Faculty of Pharmacy and Pharmaceutical Sciences, Tehran Azad University of Medical Sciences

#### City

Tehran

#### Province

Tehran

#### Postal code

1941933111

#### Approval date

2021-09-28, 1400/07/06

#### Ethics committee reference number

ir.iau.ps.rec.1400.232

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Virus clearance

#### Timepoint

Before and after intervention

#### Method of measurement

Polymerize chain reaction test using thermocycler

## Secondary outcomes

### 1

#### Description

Percentage of oxygen saturation

#### Timepoint

Before and after the intervention

#### Method of measurement

Oximeter

### 2

#### Description

clinical symptoms changes

#### Timepoint

Before and after the intervention

#### Method of measurement

Questionnaire

## Intervention groups

1

### Description

Intervention group: Patients take Sakarya-20 pharyngeal inhalation solution along with standard treatments.

Sakarya-20 contains: a complex of nanoparticles (gold, silver and iron) with a total concentration of 40 ppm soluble in water manufactured by Hayyan pharmaceutical company. The method of administration is that the patient first inhales 0.5 cc every 8 hours for two days, and from the third to the ninth day 0.5 cc solution once a day.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Islamic Azad University Hospital 320 beds

#### Full name of responsible person

Amir Hossein Moghtadar Mozhdehi

#### Street address

Hesarak, Tehran, Tehran Province

#### City

Tehran

#### Province

Tehran

#### Postal code

5661984196

#### Phone

+98 21 4486 9419

#### Email

OMID7037579@GMAIL.COM

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Personal

#### Full name of responsible person

ali maleki

#### Street address

Andisheh Town

#### City

تهران

#### Province

Tehran

#### Postal code

5661984196

#### Phone

+98 45 3253 4518

#### Email

omid7037579@gmail.com

#### Grant name

#### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

No

### Title of funding source

Personal

### 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

Other

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Azad University, Tehran Medical Sciences Branch

#### Full name of responsible person

Amir Rezazadeh

#### Position

teacher

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

Simon Bolivar Farhikhtegan Hospital

#### City

Tehran

#### Province

Tehran

#### Postal code

1996835113

#### Phone

+98 912 729 8761

#### Email

amirrezazadeh251@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Amir Hossein Moghtadar Mozhdehi

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Infectious diseases

#### Street address

Azad University, Medical Sciences Branch

#### City

tehran

#### Province

Tehran  
**Postal code**  
5661984196  
**Phone**  
+98 45 3253 4518  
**Email**  
amirtxt@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
omid moazenzadeh khyavi  
**Position**  
University student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Others  
**Street address**  
Saadi Street  
**City**  
meshkin shahr  
**Province**  
Ardabil  
**Postal code**  
5661984196  
**Phone**  
+98 45 3253 4518  
**Email**  
omid7037579@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Part of the data, such as information about the main outcome or the like, can be shared.

### When the data will become available and for how long

15 days after the publication of the article

### To whom data/document is available

Specialists and researchers in the field of health and medicine

### Under which criteria data/document could be used

The use of documents will be allowed by mentioning the source.

### From where data/document is obtainable

To Dr. Ali Maleki ali.malaki2775@gmail.com

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

Investigation and verification of the applicant, and the applicant request

### Comments