Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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

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5661984196

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Personal

Full name of responsible person
ali maleki

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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

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Assistant Professor

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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

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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