

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation the Efficacy of Sublingual Squalene for Treatment of COVID-19

Protocol summary

Study aim

Evaluation the Efficacy of Sublingual Squalene for Treatment of COVID-19

Design

Clinical trial with control group, with parallel groups, single-blind, cluster sampling, phase2 on 200 patients

Settings and conduct

The study will be conducted in public hospitals under the auspices of Mashhad University of Medical Sciences. Individuals with inclusion criteria according to the variables of age, underlying disease and disease severity will be divided into intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Molecularly confirmed COVID-19 disease or imaging over 18 years of age who need to be admitted to the ward for one of the following reasons: 1. Oxygen saturation level less than 93% (SPO2 <93%) and need support Respiratory) includes oxygen therapy (2. Decreased level of consciousness 3. Hypotension 4. dehydration and oral intolerance 5. Regardless of clinical symptoms based on underlying disease, clinical condition and paraclinical findings, be considered a High Risk patient. (Uncontrolled high blood pressure, uncontrolled diabetes, obesity, etc.) Criteria for not entering: 1. History of myocardial ischemia, heart failure, and advanced COPD. 2. Patient or patient dissatisfaction. 3. Any mental disability that impedes effective communication. 4. The existence of any physical disability that prevents the independent performance of daily activities. (Physical disability leads to disability before coronary heart disease). 5. Possibility of pregnancy and lactation 6. History of alcohol or drug abuse

Intervention groups

1. Controls who will receive only standard treatment 2. Cases who will receive squalene as well as standard treatment

Main outcome variables

Fever; SPO2; Oral tolerance; Respiratory rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200927048848N3**

Registration date: **2021-10-10, 1400/07/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-10, 1400/07/18**

Update count: **0**

Registration date

2021-10-10, 1400/07/18

Registrant information

Name

Mahmoud Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3854 5985

Email address

ebrahimimh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the Efficacy of Sublingual Squalene for

Public title

Squalene for COVID-19 treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient with definite COVID-19 confirmed by molecular or imaging methods in which the oxygen saturation level is less than 93% (SPO2 <93%) and requires respiratory support including oxygen therapy. Patient with definite COVID-19 confirmed by molecular or imaging methods with hypotension (systolic pressure less than 90) Patient with definite COVID-19 confirmed by molecular or imaging methods with Persistence of dehydration and oral intolerance after outpatient supportive care Patient with definite COVID-19 confirmed by molecular or imaging methods who are considered as high risk patient regardless of the clinical symptoms based on the underlying disease, clinical condition, and paraclinical findings. (Uncontrolled high blood pressure, uncontrolled diabetes, obesity, etc.)

Exclusion criteria:

History of myocardial ischemia, heart failure and advanced COPD Dissatisfaction of the patient or the patient's companion Any mental disability that prevents effective communication Existence of any physical disability that prevents one from performing daily activities independently. (Physical disability leads to disability before COVID-19 infection) History of alcohol or drug abuse Possibility of pregnancy and lactation

AgeFrom **18 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **200****Randomization (investigator's opinion)**

Not randomized

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

Single blinded

Blinding description

In this intervention, evaluators and analysts are blind

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Deputy of Research and Technology, Ghorashi Building, next to Hoveyze Cinema, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-06-15, 1400/03/25

Ethics committee reference number

IR.MUMS.REC.1400.143

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**

fever

Timepoint

Daily for 7 days

Method of measurement

thermometer

2**Description**

SPO2

Timepoint

daily for 7 days if hospitalization continued

Method of measurement

Pulse oxymeter

3**Description**

respiratory rate

Timepoint

daily for 7 days

Method of measurement

respiration in one minute

4

Description

food tolerance

Timepoint

daily for 7 days

Method of measurement

physician judgment

Secondary outcomes

empty

Intervention groups

1

Description

Standard treatment + sublingual drop containing squalene, 15 drops for the first day of admission and then 10 drops a day for 4 days

Category

Treatment - Drugs

2

Description

standard treatment: Since the effectiveness of antiviral drugs in reducing mortality of hospitalized patients has not been proven and on the other hand due to high costs, limited access, complications and the need for monitoring during treatment drugs such as RamedSivir, Favipiravir, protease inhibitors such as lupinavir / Ritonavir and atazanavir, interferon beta-1b and interferon beta-1e are decided separately for specific conditions. Prophylactic anticoagulant treatment in hospitalized patients is performed as follows: Heparin 5000IU SC TDS (BMI $\geq$ 40: Heparin 7500 IU SC TDS) or Enoxaparin 40 mg SC once daily (BMI $\geq$ 40: Enoxaparin 40 mg SC BID) Low-dose corticosteroids are prescribed only if the patient's symptoms improve and the need for oxygen persists despite supportive therapies and SpO₂ <90%: Dexamethasone 8 mg intravenously daily for up to 10 days or Oral prednisolone tablets 0.5mg / kg for a maximum of 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Mahmoud Ebrahimi

Street address

Zafaraniyeh Boulevard- Shandiz Torqabeh intersection

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2

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Postal code

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Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mahmoud Ebrahimi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Province

Razavi Khorasan

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available