Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Treatment of COVID-19

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
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target 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 Hoveyzeh 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 7days
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≥40: Heparin 7500 IU SC TDS)OrEnoxaparin 40 mg SC once daily (BMI ≥ 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 orOral 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
Zafaranieh 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
Street address
Deputy of Research and Technology, Ghorashi Building, next to Hoveyzeh Cinema, University Street,
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Vresearch@mums.ac.ir
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

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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Azadi Square, east door of the university campus
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Person responsible for updating data

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EbrahimiMH@mums.ac.ir

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