Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of microemulsion containing extracted squalene based on oilseeds for the treatment of COVID-19

Protocol summary

Study aim
Evaluation of the effectiveness of microemulsion containing extracted squalene for the treatment of COVID-19

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 15 patients, a random number table was used for randomization.

Settings and conduct
This study will be performed on 15 patients by injecting a dose of 20 mg of nano-structured squalene every 8 hours for 6 days. Patient symptom assessors and analysts will be blind.

Participants/Inclusion and exclusion criteria
Patients with COVID-19 who have been confirmed by CT scan and have no exclusion criteria who are in the severe and critical stages of the disease and are admitted to the Infectious Intensive Care Unit (ICU) will enter the study. Patients with a known history of myocardial ischemia and advanced heart failure and COPD, no consent of drug injection, people with any mental disability that prevents effective communication will not enter the study.

Intervention groups
All eligible subjects included the intervention group and the control group treated with chloroquine 150 (mg equivalent to 250 mg chloroquine phosphate) two tablets together on the first day and then one tablet every 12 hours for a total of 10 days or hydroxychloroquine 400 mg together on the first day and then one tablet every 12 hours to 10 days, valupinavir / ritonavir (50/200) every 12 hours, two tablets for 10 to 14 days and ribavirin 200 mg 6 tablets every 12 hours to 5 days. The intervention group, in addition to the above treatments, will be injected with nano-containing squalene 3 times a day at a dose of 20 mg for 6 days.

Main outcome variables
1- Respiratory rate less than 24 per minute 2- SPO2 content in room air more than or equal to 93% 3- No fever for 2 days 4- Oral tolerance 5- Clinical judgment of the physician

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200927048848N2**
Registration date: **2020-11-04, 1399/08/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-04, 1399/08/14**
Update count: **0**

Registration date
2020-11-04, 1399/08/14

Registrant information

Name
Mahmoud Ebrahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3854 5985

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-31, 1399/08/10

Expected recruitment end date
2020-11-30, 1399/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effectiveness of microemulsion containing extracted squalene based on oilseeds for the treatment of COVID-19

Public title
squalene and COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Covid-19 who have been confirmed by CT scan The patient has been admitted to the Intensive Care Unit (ICU) due to severe or critical condition
Exclusion criteria:
Known history of myocardial ischemia and heart failure and advanced COPD No consent of the patient or with the drug injection. 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 disease)
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Patient symptom evaluators and data analysts will be unaware of the intervention and control groups
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 Medival scienses
Street address
GHarshi building, Daneshgah Avenue.
City
Mashhad
Province
Razavi Khorasan
Postal code
1394491388
Approval date
2020-10-24, 1399/08/03
Ethics committee reference number
IR.MUMS.REC.1399.468

Health conditions studied

1

Description of health condition studied
Covid-19 disease
ICD-10 code
U07.1
ICD-10 code description
covid-19 disease

Primary outcomes

1

Description
Response to treatment criteria including respiratory rate, SPO2 in room air , presence or absence of fever for 2 days, oral tolerance, clinical judgment of the physician
Timepoint
Response to treatment will be evaluated daily, 24 hours after the first injection
Method of measurement
The number of breaths per minute will be counted by the evaluator, the blood oxygen level will be checked with a pulse oximeter, the fever will be measured sublingually using a mercury thermometer. Oral tolerance will also be recorded by evaluators.

Secondary outcomes

1

Description
Response to treatment criteria include respiratory rate less than 24 per minute, SPO2 in room air >= 93%, absence of fever for 2 days, oral tolerance, clinical judgment of the physician
Timepoint
Response to treatment will be assessed daily, 24 hours after the first injection
Method of measurement
The number of breaths per minute will be counted by the evaluator, the blood oxygen level will be checked with a pulse oximeter, the fever will be measured sublingually using a mercury thermometer. Oral tolerance will also be recorded by evaluators.

Intervention groups

1

Description
Intervention group: main treatment plus injection of 20 mg squalene microemulsion every 8 hours for 6 days
Category
Treatment - Drugs

2

Description
Control group: main treatment includes 150 mg chloroquine (equivalent to 250 mg chloroquine phosphate) two tablets together on the first day and then one tablet every 12 hours for a total of 10 days or hydroxychloroquine 400 mg together on the first day and then one tablet every 12 hours for 10 days + Lupinavir / Ritonavir (200/50) every 12 hours for 10 to 14 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Mahmood Ebrahimi
Street address
Imam Reza hosptal, Imam Reza square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Deputy of Research and Technology
Street address
Gharshi building-Daneshgah street
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South Khorasan
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9138813944
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vresreach@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
Mahmood Ebrahimi
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable