Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of slow release mucosal drug in mouth " MUCODENTOL" on disease Symptoms in COVID-19 patients.

Protocol summary

Study aim
Investigating the effect of slow release mucosal drug in mouth " MUCODENTOL" on disease Symptoms in COVID-19 patients.

Design
A randomized clinical trial with intervention / control and placebo groups on 200 patients. Excel software rand function was used for randomization. This study is not blind.

Settings and conduct
The study population consists of all infected patients with COVID-19 that hospitalized or referred to Shahid Beheshti Hospital in Qom in 1399. An infected person with Covid-19 should be diagnosed with clinical and radiographic symptoms or a positive CT scan that confirmed by two radiologists. Sampling method: Convenience sampling from qualified people who are hospitalized in Shahid Beheshti Hospital in Qom and using the method of stratified random blocks (class in order to match the groups in terms of patient severity to COVID-19) for assigning patients to the study groups.

Participants/Inclusion and exclusion criteria
-Inclusion criteria 1- Age over 18 years 2- Mental and physical ability to use this drug for three weeks 3- No history of previous allergy to drugs and similar drugs 4- Definitive diagnosis of COVID-19 5 - People are aware of time, place and person and are intellectually and mentally in a normal state. 6- Be able to communicate verbally in the interview by phone or in person 7- The patient should not be hospitalized in the intensive care unit. - exclusion criteria 1- Impossibility of a telephone interview 2- Pregnancy and lactation 3- Allergy to drugs

Intervention groups
Dentol group: mucodentol paste (carvacrol 3%) produced in Khorraman Pharmaceutical Company has been recommended to use it three times a day as well as before going to the bed and put the paste between the upper lip and gums. It does not need to be renewed until the next morning. Control group 2: They will not take any medicine or placebo.

Main outcome variables
COVID-19 symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130428013151N2**
Registration date: **2020-10-28, 1399/08/07**
Registration timing: **retrospective**

Last update: **2020-10-28, 1399/08/07**
Update count: **0**

Registration date
2020-10-28, 1399/08/07

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 1322 4918

Email address
farzan.b@lums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-25, 1399/02/06

Expected recruitment end date
2020-05-26, 1399/03/06

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of slow release mucosal drug in mouth " MUCODENTOL" on disease Symptoms in COVID-19 patients.

Public title
Evaluation of the effect of mucodentol on people with coronavirus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years old Mental and physical ability to use this drug for three weeks Lack of sensitivity to drugs and similar drugs People are aware of time, place person, are mentally and emotionally normal be able to communicate verbally for telephone interviews Infected to covid-19

Exclusion criteria:
Lack of cooperation Do not use the drug regularly Having corona and need to be hospitalized Drug sensitivity Pregnancy and lactation

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
The quadruple block method is used to assign patients to two groups A (intervention) and group B (control). To do this, first write a list of blocks and assign numbers to them. (AABB (1) - ABAB (2) - ABBA (3) - BBAA (4) - BABA (5) - BAAB (6) Then use the random number table to randomly select numbers between 1 and 6 and finally the assignment list The treatment will be based on a sequence of letters A and B. Excel software rand function was used for randomization.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences

Street address
Kamalvand Highway - Lorestan University of Medical Sciences

City
Khorramabad

Province
Lorestan

Postal code
6813833946

Approval date
2020-05-06, 1399/02/17

Ethics committee reference number
IR.LUMS.REC.1399.046

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19

Primary outcomes

1

Description
The symptoms caused by the Covid-19

Timepoint
Three times a day before bed

Method of measurement
In case of home quarantine, since it is advisable for personal protection, people should not leave the house. At the end of the first week, Second and third week, the desired symptoms will be asked and recorded as a telephone interview. In case of hospitalization, patients will be interviewed and examined.

Secondary outcomes

1

Description
fever

Timepoint
daily

Method of measurement
Thermometer

2

Description
Respiratory-general symptoms
Timepoint
daily
Method of measurement
yes/no

Intervention groups

1

Description
Dental Intervention Group: mucoadhesive slow-release paste mucodentol (carvacrol 3%) produced in Khorraman Pharmaceutical Company located in Khorramabad has been recommended to use it three times a day as well as before going to the bed by participants and put the paste between the upper lip and gums.
Category
Treatment - Drugs

2

Description
Control group: will not take any medicine or placebo.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital-Qom
Full name of responsible person
Behrooz Farzan
Street address
Qom Province, Qom, Beheshti Blvd, Iran
City
Qom
Province
Ghoum
Postal code
3713649373
Phone
+98 25 3612 2000
Email
tsabokbar@muq.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Ebrahim Fallahi
Street address
University of Medical Sciences, Shahid Anoushirvan Rezaei Square,Moallem St,Khorramabad,Lorestan,Iran
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Khorramabad
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Postal code
6813833946
Phone
+98 66 3330 0661
Email
publicrelation@lums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Behrooz Farzan
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Bimarestan street, Shohada Ashayer hospital
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farzan.b@lums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person
Behrooz Farzan

Position
Assistant Professor

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available