

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 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

Ghous

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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Lorestan

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

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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