Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of slow release mucoadhesive paste of" MUCODENTOL " in oral vestibule on symptoms of COVID-19 disease in staffs of hospitals of LUMS

Protocol summary

Study aim
Evaluation of slow release mucoadhesive paste of" MUCODENTOL " in oral vestibule on symptoms of COVID-19 disease in staff of hospitals of LUMS

Design
Clinical trial with intervention-control groups. A blind, accidental strain, Phase 1 on 1300 patients. The rand function of the Excel software was used for randomization.

Settings and conduct
In this study, 1,600 working staffs in the ICU and emergency departments and inpatient wards of the dependent Hospital of LUMS will enter the study. Staffs taking part in the study are asked to apply two drops of the drug three times a day in the area between the upper lip and upper jaw.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: - Mental and physical ability to use this drug for three weeks - Lack of sensitivity to drugs and similar drugs - Staffs working in the ICU / emergency department/wards/etc - Men and women - Be able to communicate for a telephone interview Criteria for leaving the study: - Lack of cooperation - Impossibility of a telephone interview - Do not use the drug regularly - Drug sensitivity - Pregnancy and lactation

Intervention groups
1- Dentol group: Mocodentol ointment is given to them and they are asked to use it three times a day before going to bed and apply two drops of ointment in the upper oral vestibule. It does not need to be renewed until the next morning. 2- Control group: They will not take any medicine or pharmaceuticals.

Main outcome variables
Respiratory symptoms --- General Severe sore throat Severe dry cough Severe shortness of breath Migration intensity The severity of erythema Severity of fever

General information

Reason for update

Acronym
COVID-19

IRCT registration information
IRCT registration number: **IRCT20090304001739N3**
Registration date: **2020-09-01, 1399/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-01, 1399/06/11**
Update count: **0**

Registration date
2020-09-01, 1399/06/11

Registrant information

Name
sepideh vahabi

Name of organization / entity
lorestan medical science university

Country
Iran (Islamic Republic of)

Phone
+98 66 1422 8071

Email address
vahabi.s@lums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-02, 1399/01/14

Expected recruitment end date
2020-09-05, 1399/06/15

Actual recruitment start date
2020-05-09, 1399/02/20

Actual recruitment end date
2020-09-05, 1399/06/15

Trial completion date
2020-09-05, 1399/06/15

Scientific title
Evaluation of slow release mucoadhesive paste of" MUCODENTOL " in oral vestibule on symptoms of COVID-19 disease in staffs of hospitals of LUMS

Public title
Evaluation of slow release mucoadhesive paste of" MUCODENTOL " in oral vestibule on symptoms of COVID-19 disease in hospital staff
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
-Mental and physical ability to use this drug for three weeks- Lack of sensitivity to drugs and similar drugs- staffs working in the ICU / Emergency / Hospital wards of the Corona Center for Nomadic Martyrs- Men and women - Be able to communicate for a telephone interview
Exclusion criteria:
-Lack of cooperation- Impossibility of telephone interviews- Do not use the drug regularly- - Drug sensitivity- Pregnancy and lactation
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
0
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **1600**
Actual sample size reached: **1600**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
All data collector didnot know about which groups staffs are in.
Placebo
Not used
Assignment
Parallel
Other design features
as placebo dosent have special smell of carvacrol we have to use metod of "use ot not use " of drug

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Lorestan University of Medical Sciences
Street address
kamalvand-LUMS
City
khoramabad
Province
Lorestan
Postal code
6587349807
Approval date
2020-04-12, 1399/01/24
Ethics committee reference number
IR.LUMS.REC.1399.013

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, PREVENTION

Primary outcomes

1

Description
Detection and severity if covid 19 disease
Timepoint
at the end of the first - second - third week of participation in study
Method of measurement
Examination by a doctor

Secondary outcomes

1

Description
Respiratory-general symptoms
Timepoint
weekly
Method of measurement
Mild - moderate - severe

2

Description
fever
Timepoint
weekly
Method of measurement
Thermometer

Intervention groups

1

Description
Intervention group: Evaluation of the effect of mucodentol continuous adhesive mucus in the mouth on the occurrence of COVID-19 disease symptoms in nurses working at the end of the first - second - third week of drug use
Category
Treatment - Drugs

2

Description
Control group: They will not take any medication or medication.
Category
N/A

3

Description
we didnt find placebo like carvacrol smell
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
dependent hospital of LUMS
Full name of responsible person
Sepideh Vahabi
Street address
Enghelab street, Shohada Ashayer hospital
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vahabi.s@lums.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
Kamalvand Highway - Lorestan University of Medical Sciences
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6813833946
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publicrelation@lums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
KHORRAMAN pharmacy
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Sepideh vahabi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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professor

Latest degree

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Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

If published as an article, Relevant sections are published

When the data will become available and for how long

starts after publishing of results

To whom data/document is available

Available to the public when published

Under which criteria data/document could be used

In our study, all findings will be available for public after analysis and publication

From where data/document is obtainable

All findings are listed in the article and do not need to be referenced

What processes are involved for a request to access data/document

All findings are listed in the article and do not need to be referenced

Comments