

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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 mucodental 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

##### City

Khorramabad

##### Province

Lorestan

##### Postal code

۶۵۷۴۸۳۹۸۲۳

##### Phone

+98 66 3322 9923

##### Email

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

#### City

Khorramabad

#### Province

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?

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

##### Street address

Enghelab Street - Shohada Ashayer Hospital

##### City

Lorestan

##### Province

Lorestan

##### Postal code

6813833946

##### Phone

+98 66 3342 8071

##### Email

vahabi.s@lums.ac.ir

## Person responsible for scientific 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

**Street address**

Enghelab Street - Shohada Ashayer Hospital

**City**

Khorramabad

**Province**

Lorestan

**Postal code**

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**Email**

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**Person responsible for updating data**

**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

**Street address**

enghelab Street - Shohada Ashayer Hospital

**City**

Khorramabad

**Province**

Lorestan

**Postal code**

6813833946

**Phone**

+98 66 3342 8071

**Email**

vahabi.s@lums.ac.ir

**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**