

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### Evaluation of slow release mucoadhesive paste of” Mucodentol “ on symptoms of COVID-19 disease in non infected family members of infected patients by COVID-19

#### Protocol summary

##### Study aim

Evaluation of slow release mucoadhesive paste of” Mucodentol “ on symptoms of COVID-19 disease in non infected family members of infected patients by COVID-19

##### Design

Clinical trial with intervention-control and placebo groups. A blind, accidental strain, Phase 1 on 600 patients. The rand function of the Excel software was used for randomization.

##### Settings and conduct

In this study, a double-blind clinical trial is performed on the covid-19 patient's companions. 600 family members of coronary patients who have been diagnosed with the disease and have been referred or hospitalized in Qom will be included in the study. These patient companions, both men and women over the age of 18, with any level of education and marital status, will enter the plan if they agree.

##### Participants/Inclusion and exclusion criteria

Study entry criteria: 1- Age over 18 years 2- Mental and physical ability to use this drug for three weeks 3- The presence of a person with COVID-19 in the family 4- To be able to communicate verbally for a telephone interview Exclusion criteria: 1-Covid-19 infection 2- Drug sensitivity 3- Underlying diseases: Cardiovascular diseases, Diabetes, Immune system deficiency 4- Pregnancy or 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- Plasbo group: Plasbo ointment is given to them and they are asked to use the ointment in the above order and to apply two drops of the ointment in the upper oral vestibule. 3- 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

##### IRCT registration information

IRCT registration number: **IRCT20200711048076N1**

Registration date: **2020-09-05, 1399/06/15**

Registration timing: **retrospective**

Last update: **2020-09-05, 1399/06/15**

Update count: **0**

##### Registration date

2020-09-05, 1399/06/15

##### Registrant information

##### Name

Sahar Behzad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8820 0061

##### Email address

s.behzad@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2020-07-22, 1399/05/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of slow release mucoadhesive paste of Mucodentol " on symptoms of COVID-19 disease in non infected family members of infected patients by COVID-19

**Public title**

The effect of mucodentol on covid-19 symptoms

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age over 18 years. Mental and physical ability to use this drug for three weeks. Lack of sensitivity to similar drugs.

Existence of a person with COVID -19 in the family.

People are aware of time, place and person, are in a natural state mentally and mentally, Be able to communicate verbally for a telephone interview.

**Exclusion criteria:**

Covid-19 infection Drug sensitivity Underlying diseases: Cardiovascular diseases, Diabetes, Immune system deficiency,... Pregnancy or lactation

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **600**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomized block design (4 blocks) is planned as: group A (intervention) and group B (control). At first, the list of blocks is prepared and numbers are assigned. AAB(1)- ABAB(2)- ABBA(3)- BBAA(4)- BABA(5)- BAAB(6) Then numbers between 1 to 6 will be selected by using random number table and finally, assigned list is based on A and B sequence.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

-

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

School of Pharmacy, Shahid Beheshti University of Medical Sciences, ValieAsr-Hashemi Rafsanjani Junction

**City**

Tehran

**Province**

Tehran

**Postal code**

1991953381

**Approval date**

2020-04-06, 1399/01/18

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1399.042

**Health conditions studied****1****Description of health condition studied**

COVID-19

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Severity of dry coughs

**Timepoint**

At the end of the first - second and third week of medication use

**Method of measurement**

Phone call, Self-declaration and fill the related questionnaire

**2****Description**

Severity of a sore throat

**Timepoint**

At the end of the first - second and third week of medication use

**Method of measurement**

Phone call, Self-declaration and fill the related questionnaire

**3****Description**

Severity of a shortness of breath

**Timepoint**

At the end of the first - second and third week of

medication use

N/A

#### **Method of measurement**

Phone call, Self-declaration and fill the related questionnaire

#### **4**

##### **Description**

severity of a myalgia

##### **Timepoint**

At the end of the first - second and third week of medication use

##### **Method of measurement**

Phone call, Self-declaration and fill the related questionnaire

#### **5**

##### **Description**

Severity of arthralgia

##### **Timepoint**

At the end of the first - second and third week of medication use

##### **Method of measurement**

Phone call, Self-declaration and fill the related questionnaire

#### **6**

##### **Description**

Severity of fever

##### **Timepoint**

At the end of the first - second and third week of medication use

##### **Method of measurement**

Phone call, Self-declaration and fill the related questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: All the non-infected family members who live with an infected COVID-19. Every one will receive 3 mucodentol 3% (Khorraman co) tubes for 3 weeks . They will take it on oral upper vestibule BD (ones before sleeping). There is no need to retake it.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Control group: They do not receive Mucodentol but receive all the general advises and self-protection protocols by Iranian ministry of health and medical education for prevention of COVID-19 infection

##### **Category**

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Qom Hospitals

###### **Full name of responsible person**

Nina Farzan

###### **Street address**

Qom, Bazaar Junction, at the beginning of 19th Dey Street (Bajak 1), Kamkar Hospital - Arabnia

###### **City**

Qom

###### **Province**

Ghous

###### **Postal code**

1991953381

###### **Phone**

+98 25 3771 3511

###### **Email**

dr.ninafarzan@gmail.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

###### **Full name of responsible person**

Sahar Behzad

###### **Street address**

School of Pharmacy, Shahid Beheshti University of Medical Sciences, Valieasr-Hashemi Rafsanjani Junction

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1991953381

###### **Phone**

+98 21 8820 0061

###### **Email**

s.behzad@sbmu.ac.ir

###### **Web page address**

<https://sbmu.ac.ir>

###### **Grant name**

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###### **Grant code / Reference number**

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###### **Is the source of funding the same sponsor organization/entity?**

Yes

###### **Title of funding source**

Shahid Beheshti 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**  
Behruz Farzan  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Khoram-Abad University of Medical Sciences, Shahid  
Anushirvan Rezaie Square, Moallem Street  
**City**  
Khoram-Abad  
**Province**  
Lorestan  
**Postal code**  
6813833946  
**Phone**  
0098 6633300661-5  
**Email**  
B\_farzan41@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Khoram-Abad University of Medical Sciences  
**Full name of responsible person**  
Behruz Farzan  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Khoram-Abad University of Medical Sciences, Shahid  
Anushirvan Rezaie Square, Moallem Street  
**City**  
Khoram-Abad  
**Province**

Lorestan  
**Postal code**  
6813833946  
**Phone**  
0098 6633300661-5  
**Email**  
B\_farzan41@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Sahar Behzad  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Pharmacognosy  
**Street address**  
School of Pharmacy, Shahid Beheshti University of  
Medical Sciences, ValieAsr-Hashemi Rafsanjani  
Junction  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1991953381  
**Phone**  
+98 21 8820 0061  
**Email**  
s.behzad@sbmu.ac.ir

## 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

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

Not applicable

### Data Dictionary

Not applicable