

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 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

Grant code / Reference number

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