Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+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. AABB(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

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

N/A

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sahar Behzad

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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

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Person responsible for updating data

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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