

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 May 2021

Evaluation of the Effectiveness of Mouthwashes in Early Reducing the mouth Viral Load Among COVID-19 Patients: A double-blind randomized clinical trial

Protocol summary

Study aim

Determining the effect of different mouthwashes in early reduction of viral load inside COVID-19 patients' mouths

Design

Sixty patients are randomly assigned to intervention group 1, intervention 2 and intervention 3 or control group. The study phase is 3

Settings and conduct

This study is a randomized, double-blind clinical trial that will be performed in adult patients (aged 18 to 70 years) with a diagnosis of COVID-19 infection referred to Farshchian Hospital in Hamadan.

Participants/Inclusion and exclusion criteria

Clinical diagnosis of COVID-19 infection based on the opinion of the treating physician based on national guidelines, Patients with mild to moderate disease, Patients with previous underlying oral disease, Patients with inability to properly perform the mouthwash protocol, Patients with thyroid disorders.

Intervention groups

In intervention group 1, patients will gargle and rinse 20 cc of 2% Povidone-iodine mouthwash in the mouth for 20 seconds. In intervention group 2, patients will gargle and rinse 20 cc of 1% hydrogen peroxide mouthwash for 20 seconds in the mouth. In intervention group 3, patients will gargle and rinse 20 cc of Cetylpyridinium chloride mouthwash for 20 seconds. In the patient control group, 20 cc of normal saline mouthwash will be gargled and rinsed inside the mouth for 20 seconds.

Main outcome variables

Early reduction of viral load

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170117032025N7**

Registration date: **2020-07-12, 1399/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-12, 1399/04/22**

Update count: **0**

Registration date

2020-07-12, 1399/04/22

Registrant information

Name

Arash Khalili

Name of organization / entity

Hamadan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0320

Email address

a.khalili@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-11, 1399/04/21

Expected recruitment end date

2020-10-12, 1399/07/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effectiveness of Mouthwashes in Early Reducing the mouth Viral Load Among COVID-19

Patients: A double-blind randomized clinical trial

Public title

Effectiveness of Mouthwashes in Early Reducing the mouth Viral Load Among COVID-19 Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical diagnosis of COVID-19 infection based on the opinion of the treating physician based on national guidelines Patients with mild to moderate disease

Exclusion criteria:

Patients with previous underlying oral disease Patients with inability to properly perform the mouthwash protocol Patients with thyroid disorders

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

We prepare four sheets of paper and write on one sheet the letter P meaning Povidone-iodine, O meaning hydrogen peroxide, C meaning Cetylpyridinium, and N meaning normal saline. Mix the sheets and place them in the desk drawer. Upon referral to each of the eligible patients, one of the sheets will be randomly removed and assigned to one of the three intervention or control groups, and this will continue until the sample size is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

All four groups will receive a mouthwash with the same appearance, which is marked with a code, and the patient and the person responsible for RT-PCR testing and the person responsible for collecting the type of drug used by the patient will be unaware.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan University of Medical Sciences

Street address

Shahid Fahmideh boulevard

City

Hamadan

Province

Hamadan

Postal code

7615665175

Approval date

2020-06-04, 1399/03/15

Ethics committee reference number

IR.UMSHA.REC.1399.235

Health conditions studied

1

Description of health condition studied

Early reduction in COVID-19 viral load

ICD-10 code

D10.3

ICD-10 code description

Other and unspecified parts of mouth

Primary outcomes

1

Description

Early reduction of viral load in the mouth of COVID-19 patients

Timepoint

A sample of oropharyngeal swap will be taken from patients to check for viral load before intervention. Patients then use 20 cc of the appropriate mouthwash, based on the assigned group, which will be practically taught by the researcher on how to use it. After 30 minutes from the beginning of the intervention, the second sample of oropharyngeal swap will be determined to determine the virus load. After preparation, all samples will be placed in a tube containing a special medium for transmission (VTM) and will be transferred to the specialized reference laboratory COVID-19 of Hamadan University of Medical Sciences to determine the load of the virus by standard RT-PCR method

Method of measurement

A sample of an oropharyngeal swap will be taken from patients to check for viral load before intervention. After 30 minutes from the start of the intervention, a second oropharyngeal swap will be performed to determine the virus load.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In intervention group 1, patients will gargle and rinse 20 cc of 2% Povidone-iodine mouthwash in the mouth for 20 seconds.

Category

Treatment - Drugs

2

Description

Intervention group: In intervention group 2, patients will gargle and rinse 20 cc of 1% hydrogen peroxide mouthwash for 20 seconds in the mouth.

Category

Treatment - Drugs

3

Description

In intervention group 3, patients will gargle and rinse 20 cc of Cetylpyridinium chloride mouthwash for 20 seconds.

Category

Treatment - Drugs

4

Description

Control group: In the patient control group, 20 cc of normal saline mouthwash will be gargled and rinsed inside the mouth for 20 seconds.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Farshchian specialized and sub-specialized hospital in Hamadan

Full name of responsible person

Dr Ali Heidari

Street address

Shahid Fahmideh street

City

Hamadan

Province

Hamadan

Postal code

6517838698

Phone

+98 81 3525 0182

Email

aliheidari55@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeed Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Ali Heidari

Position

Faculty Member

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Ali Heidari_

Position

Faculty Member

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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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

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