

# 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

##### Street address

Shahid Fahmideh street

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838698

##### Phone

+98 81 3525 0182

##### Email

aliheidari55@gmail.com

#### 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

Shahid Fahmideh street

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## Person responsible for scientific inquiries

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**Position**

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**Latest degree**

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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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**Position**

Faculty Member

**Latest degree**

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**Other areas of specialty/work**

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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