Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

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

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Iran (Islamic Republic of)

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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 boulvard
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
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6517838698
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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