

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of 0.1% sodium hypochlorite mouthwash versus normal saline in early reducing intraoral viral load among patients with COVID-19: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of 0.1% sodium hypochlorite mouthwash versus normal saline in early reducing intraoral viral load among patients with COVID-19

Design

This is a double-blind randomized clinical trial, phase III, in which 118 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with COVID-19 referring to the Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 70 years; Mild to moderate Covid-19 disease; Need for hospitalization; Exclusion criteria: Pregnancy or breastfeeding; Oral disease; Simultaneous use of other mouthwashes; Patients under mechanical ventilation; Patients with decreased level of consciousness;

Intervention groups

Intervention group: Gargling 0.1% sodium hypochlorite mouthwash 20 ml once for 30 seconds Control group: Gargling normal saline 20 ml once for 30 seconds

Main outcome variables

Primary outcome: Oral viral load

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N398**
Registration date: **2021-06-20, 1400/03/30**

Registration timing: **prospective**

Last update: **2021-06-20, 1400/03/30**

Update count: **0**

Registration date

2021-06-20, 1400/03/30

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-06, 1400/04/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of 0.1% sodium hypochlorite mouthwash versus normal saline in early reducing intraoral viral load among patients with COVID-19: a double-blind randomized

clinical trial

Public title

Effect of 0.1% sodium hypochlorite mouthwash versus normal saline in early reducing intraoral viral load among patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 70 years; Mild to moderate Covid-19 disease; Need for hospitalization;

Exclusion criteria:

Pregnancy or breastfeeding; Oral disease; Simultaneous use of other mouthwashes; Patients under mechanical ventilation; Patients with decreased level of consciousness;

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **118**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IR.UMSHA.REC.1400. 236

Street address

Vice-chancellor for Research and Technology,
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Approval date

2021-06-12, 1400/03/22

Ethics committee reference number

IR.UMSHA.REC.1400. 236

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Oral viral load

Timepoint

Before the intervention and 30 minutes after intervention

Method of measurement

Using oropharyngeal swab

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Gargling 0.1% sodium hypochlorite mouthwash 20 ml once for 30 seconds

Category

Treatment - Drugs

2

Description

Control group: Gargling normal saline 20 ml once for 30

seconds
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital in Hamadan city
Full name of responsible person
Dr Maryam Mehrpooya
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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
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Full name of responsible person

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Professor of Epidemiology

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