

# 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)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

#### 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  
**Street address**  
Sina Hospital, Mirzadeh Eshghi Ave.  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3827 4184  
**Email**  
m\_mehrpooya2003@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Saeid Bashirian  
**Street address**  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0717  
**Email**  
info.research@umsha.ac.ir  
**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 Maryam Mehrpooya  
**Position**  
Pharmacologist  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0572  
**Email**  
m\_mehrpooya2003@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Abbas Taher  
**Position**  
Anesthesiologist  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0572  
**Email**  
t\_anesthesia@yahoo.com

## Person responsible for updating data

poorolajal@umsha.ac.ir

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

## 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