Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparative study of the effect of two solutions of Chlorhexidine and sodium bicarbonate mouthwash on the onset of Covid-19 related symptoms in vaccinated operating room staff

Protocol summary

Study aim

Comparative determination of the effect of two solutions of Chlorhexidine and sodium bicarbonate mouthwash on the onset of symptoms attributed to Covid-19 in vaccinated operating room staff of selected hospitals of Isfahan University of Medical Sciences in 2022

Design

A controlled clinical trial with parallel, double-blind, randomized groups on 120 patients. To divide the subjects into intervention and control groups, random allocation method and table of random numbers will be used.

Settings and conduct

This study will be performed in selected hospitals of Isfahan. The intervention groups will receive Chlorhexidine mouthwash and sodium bicarbonate mouthwash and the control group receives placebo. Mouthwash and placebo will be used for two weeks, twice a day, 15 ml each time for one minute. From the start of mouthwash solutions until four weeks later, the studied samples will be monitored. To double-blind the study, participants will be unaware of the type of mouthwash solution and the data analyzer will be unaware of the details of the grouping.

Participants/Inclusion and exclusion criteria

Get at least two doses of the vaccine, Personnel range of 18-60 years, Do not get Covid-19 in the last two months, No symptoms of systemic infection, Do not take immunosuppressive drugs, No history of allergy to mouthwash solutions, At least 2 weeks have passed since the second dose of the vaccine was given, No pregnancy, No breastfeeding

Intervention groups

The intervention groups will receive chlorhexidine mouthwash and sodium bicarbonate mouthwash, and the control group received placebo (water). Mouthwash and placebo will use for two weeks, twice a day, 15 ml each time for one minute. From the start of mouthwash solutions until four weeks later, the samples will be monitored for symptoms. If necessary, PCR test will also be taken.

Main outcome variables

Covid-19 symptoms, PCR test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220328054364N1**
Registration date: **2022-06-21, 1401/03/31**
Registration timing: **prospective**

Last update: **2022-06-21, 1401/03/31**
Update count: **0**

Registration date

2022-06-21, 1401/03/31

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-06, 1401/04/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of two solutions of Chlorhexidine and sodium bicarbonate mouthwash on the onset of Covid-19 related symptoms in vaccinated operating room staff

Public title

Evaluation of the effectiveness of Chlorhexidine and sodium bicarbonate mouthwash solutions on the onset of Covid-19 symptoms

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Personnel with an age range of 18-60 years Get at least two doses of the vaccine At least two weeks have passed since the second dose of the vaccine was given

Exclusion criteria:

Pregnant personnel Breastfeeding period History of allergy to mouthwash solutions Taking immunosuppressive drugs Having Covid-19 in the last two months Having symptoms of systemic infection

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, the researcher first enters the study of the operating room personnel by calling in the research environment and explaining the title, taking into account the inclusion criteria, by easy sampling method. In order to balance the number of samples assigned to each of the study groups, the block randomization method will be used and the size of each block will be considered 3. For random allocation with random blocks, a valid website (https://www.sealedenvelope.com/simple-randomiser/v1/lists) will be used, then the samples will be placed in each of the intervention or control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind the study and not inform the staff about the type of mouthwash, the type of solution is not written on the bottles and the type of solution will be determined using coding. Also the bottles are made similar and opaque, and the food coloring is used to match the color of the solutions.In addition, the person analyzing the data will not know the details of the groupings.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2022-06-11, 1401/03/21

Ethics committee reference number

IR.MUI.NUREMA.REC.1401.044

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

B97.21

ICD-10 code description

SARS-associated coronavirus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

headache

Timepoint

For 4 weeks, from the beginning of using mouthwash

Method of measurement

Record in the checklist of symptoms

2

Description
Temperatures
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Medical thermometer (Record in the checklist of symptoms)

3

Description
Cough
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

4

Description
Shortness of breath
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

5

Description
Muscular pain
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

6

Description
Sore throat
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

7

Description
Runny nose and nasal congestion
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

8

Description
Sneezing
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

9

Description
Lethargy
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

10

Description
dizziness
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

11

Description
Anorexia
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

12

Description
Diarrhea
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

13

Description
Vomit
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

14

Description
Decreased sense of taste
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

15

Description
Decreased sense of smell
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

16

Description
Skin rash
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

17

Description
Red and irritated eyes
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

18

Description
lacrimation
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

19

Description
Weakness
Timepoint
For 4 weeks, from the beginning of using mouthwash
Method of measurement
Record in the checklist of symptoms

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group 1, after preparing dark colored medicine glass bottles that are uniform, the researcher prepares 0.2% Chlorhexidine solution under the brand name Vi-one in the form of mouthwash solutions prepared from the pharmacy and only the bottle is changed. The mouthwash solution is used once in the morning and once in the evening in the amount of 15 ml for one minute. Before using mouthwash, you must use a toothbrush and eat and drink is forbidden for at least half an hour after using mouthwash. Due to the fact that some toothpastes may have antimicrobial properties, in this study, the researcher prepared plain mint toothpaste from Goltash Company and provided samples to all three groups. This toothpaste is simple and without properties. It is antimicrobial. The duration of mouthwash is two weeks, then mouthwash is stopped and personnel are followed for four weeks from the first day of mouthwash to check the onset of symptoms of Quid-19. Personnel are checked. During the four weeks that the staff is monitored, they must record and report their symptoms once a week in the symptom checklist, and if they observe any suspicious signs other than one week apart, they must Make a note of the checklist mentioned. At one-week intervals, a total of four staff members record their symptoms in a symptom checklist four times over a four-week period. The research units are asked to inform the researcher when any of the signs that have already been explained to them appear. The researcher records each of the signs that appear along with the personnel details. PCR testing will be performed on staff if required. By creating a group in WhatsApp software and daily consumption table of mouthwash, the use of mouthwash is reminded and recorded. How to use mouthwash and its important points are written on the bottles and in addition it is explained orally.
Category
Early detection

2

Description
In intervention group 2, the researcher prepares dark colored medicine glass bottles that are uniform. Sodium bicarbonate solution is prepared by the researcher as a mouthwash solution of 5.7% (per 100 ml of water containing 5.7 grams of sodium bicarbonate) using an accurate scale with Imperial brand and graduated glasses and after dissolving it , Is poured into glass bottles. The mouthwash solution is used once in the morning and once in the evening in the amount of 15 ml for one minute. Before using mouthwash, you must use a toothbrush and eat and drink is forbidden for at least half an hour after using mouthwash. Due to the fact that some toothpastes may have antimicrobial properties, in this study, the researcher prepared plain mint toothpaste from Goltash Company and provided samples to all three groups. This toothpaste is simple and without properties. It is antimicrobial. The duration of mouthwash is two weeks, then mouthwash is stopped and personnel are followed for four weeks from the first day of mouthwash to check the onset of symptoms of Quid-19. Personnel are checked. During the four weeks that the staff is monitored, they must record and report their symptoms once a week in the symptom checklist, and if they observe any suspicious signs other than one week apart, they must Make a note of the checklist mentioned. At one-week intervals, a total of four staff members record their symptoms in a symptom checklist four times over a four-week period. The research units are asked to inform the researcher when any of the signs that have already been explained to them appear. The researcher records each of the signs that appear along with the personnel details. PCR testing will be performed on staff if required. By creating a group in WhatsApp software and daily consumption table of mouthwash, the use of mouthwash is reminded and recorded. How to use mouthwash and its important points are written on the bottles and in addition it is explained orally.
Category
Early detection

3

Description

Control group: Control group: The third mouthwash of the study is a placebo. In this study, purified water is considered. Due to the use of piped drinking water in the preparation of sodium bicarbonate solution, for the placebo, purified drinking water is also piped. Used. According to the rules of placebo, in order for these three solutions to be the same shape and not to cause a problem in blinding, and according to the fact that the Chlorhexidine solution prepared is blue, the researcher added a food coloring of blue liquid which is soluble in water. It uses a small amount of the other two mouthwashes, purified water and sodium bicarbonate. The permissible oral color of the liquid is added with a dropper and in a certain volume of the mouthwash solution and compared with the Chlorhexidine solution to make them look similar in color. The mouthwash solution is used once in the morning and once in the evening in the amount of 15 ml for one minute. Before using mouthwash, you must use a toothbrush and eat and drink is forbidden for at least half an hour after using mouthwash. Due to the fact that some toothpastes may have antimicrobial properties, in this study, the researcher prepared plain mint toothpaste from Goltash Company and provided samples to all three groups. This toothpaste is simple and without properties. It is antimicrobial. The duration of mouthwash is two weeks, then mouthwash is stopped and personnel are followed for four weeks from the first day of mouthwash to check the onset of symptoms of Quid-19. Personnel are checked. During the four weeks that the staff is monitored, they must record and report their symptoms once a week in the symptom checklist, and if they observe any suspicious signs other than one week apart, they must Make a note of the checklist mentioned. At one-week intervals, a total of four staff members record their symptoms in a symptom checklist four times over a four-week period. The research units are asked to inform the researcher when any of the signs that have already been explained to them appear. The researcher records each of the signs that appear along with the personnel details. PCR testing will be performed on staff if required. By creating a group in WhatsApp software and daily consumption table of mouthwash, the use of mouthwash is reminded and recorded. How to use mouthwash and its important points are written on the bottles and in addition it is explained orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Afsaneh Aminbitaraf

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2

Recruitment center

Name of recruitment center

Ayatollah Kashani hospital

Full name of responsible person

Farhad Jalali

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haniehkarami@nm.mui.ac.ir

3

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Maryam Azari Poor

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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
Esfahan 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
Hanieh Karami Chamgordani
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Bachelor
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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Once the individuals are unidentifiable, all data will be published, including information about the main outcome as well as contextual variables such as the age and sex of the study participants.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working at academic institutions will have access to the data.

Under which criteria data/document could be used

Use of data for 1. Therapeutic 2. Research purposes

From where data/document is obtainable

Hanieh Karami Chamgordani haniehkarami@nm.mui.ac.ir

What processes are involved for a request to access data/document

Send a request by contact and provide evidence for use in research or treatment and receive data

Comments