Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Evaluating the effect of gargling with Hydrogen Peroxide 1% and Povidine Iodine 0.25% on viral load of SARS-CoV-2 in covid19 patients ; A pilot randomized clinical trial

Protocol summary

Study aim

The aim of this study is to evaluate the effect of oral rinse of povidine iodine and hydrogen peroxide mouthwash in comparison with normal saline on viral load in confirmed covid 19 patients who may undergo dental treatment.

Design

this double blinde clinical trial having control group and parallel groups and randomized phase2 in 60 participants . block randomization method using the online RANDOM.ORG software was done.

Settings and conduct

The target population will be consisted of patients of both sex who are hospitalized in shahid faghihi hospital, Namazi hospital and Aliasghar hospital, Shiraz University Of Medical Sciences, Shiraz, IRAN due to Covid -19 disease. All the participants, the nurse which will do the sampling and the author will be blinded from each other.

Participants/Inclusion and exclusion criteria

The inclusion criteria are age 18-50,and the hospitalized confirmed covid 19 patients. Exclusion crireria are having any systemic disease or medications that may interact with Povidine Iodine and-or Hydrogen Peroxide, patients who are not feeling well, not cooperative patients, and those who are not willing to participate in the study

Intervention groups

In each group two saliva samples is needed. first at 0 hour (before gargle), and the second, 5 to 10 minutes after using mouthwashes. Group A (n=20) patients on 10 ml gargle using 0.25% Povidone-Iodine, for 20-30 seconds. Group B (n=20) patients will be subjected to 10 ml gargle of 1% Hydrogen peroxide for 20-30 seconds. Group C (n=20) will serve as positive control. These will be given simple normal saline gargle for 20-30 seconds,

Main outcome variables

To determine the viral load before and after the intervention.

General information

Reason for update

Acronym

SARS-COV2, Covid19

IRCT registration information

IRCT registration number: **IRCT20201212049681N1**
Registration date: **2021-02-28, 1399/12/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-28, 1399/12/10**
Update count: **0**

Registration date

2021-02-28, 1399/12/10

Registrant information

Name

zahra rajabzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3631 5271

Email address

dr.zrajabzadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

2021-01-20, 1399/11/01

Actual recruitment end date

2021-03-19, 1399/12/29

Trial completion date

2021-04-19, 1400/01/30

Scientific title
Evaluating the effect of gargling with Hydrogen Peroxide 1% and Povidine Iodine 0.25% on viral load of SARS-CoV-2 in covid19 patients ; A pilot randomized clinical trial

Public title
Evaluating the effect of gargling with Hydrogen Peroxide 1% and Povidine Iodine 0.25% on viral load of SARS-CoV-2 in covid19 patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
having age 18-50, those who are hospitalized and have confirmed covid 19 viral contamination.
Exclusion criteria:
having any systemic disease or medications that may interact with Povidine Iodine and-or Hydrogen Peroxide patients who are not feeling well, not cooperative patients, and those who don’t want to participate in the study

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
1 sample before intervention and one sample after intervention
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients Will be equally divided into three experimental groups, namely, the A,B,C group. The allocation of the participants will be based on the block randomization method using the online RANDOM.ORG software. Each random number will be placed in a sealed opaque envelope and subsequently, each participant randomly will pick one envelope corresponding to either the A,B, orC group.

Blinding (investigator's opinion)
Double blinded

Blinding description
To ensure both the participants and clinicians will be blinded to the clinical trial,all the participants, the nurse which will do the sampling and the author will be blinded from each other, and are not aware of the mouthwash that is used.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University Of Medical Sciences
Street address
Department of Endodontics, School of Dentistry, Ghasrdast Street, Shiraz, Iran,
City
Shiraz
Province
Fars
Postal code
71956-15878

Approval date
2021-01-09, 1399/10/20

Ethics committee reference number
IR. SUMS. DENTAL.REC.1399.186

Health conditions studied

1

Description of health condition studied
Covid-19

ICD-10 code
RAO1.0

ICD-10 code description
severe acute respiratory syndrome corona virus

Primary outcomes

1

Description
viral load before the intervention, viral load after the intervention

Timepoint
before intervention and 5-10 minutes after intervention

Method of measurement
real-time reverse transcriptase polymerase chain reaction (rRT-PCR)

Secondary outcomes

1

Description

viral transmission in saliva

Timepoint

before the intervention and 5-10 minutes after the intervention

Method of measurement

real-time reverse transcriptase polymerase chain reaction (rRT-PCR)

Intervention groups

1

Description

intervention group: Group A (n=20) patients on 10 ml gargle using 0.25% Povidone-Iodine, for 20-30 seconds,

Category

Treatment - Drugs

2

Description

intervention group: Group B (n=20) patients will be subjected to 10 ml gargle using 1% Hydrogen peroxide for 20-30 seconds.

Category

Treatment - Drugs

3

Description

Control group: Group C (n=20) will serve as positive control. These will be given simple normal saline gargles for 20-30 seconds,

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi hospital

Full name of responsible person

Mahdi Sedigh Shams

Street address

Department of Endodontics, School of Dentistry, Ghasrdast Street, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71956-15878

Phone

+98 71 3832 3435

Email

adla@sums.ac.ir

Web page address

https://sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Azadeh Andishe tadbir

Street address

: Department of Endodontics, School of Dentistry, Ghasrdast Street, Shiraz, Iran,

City

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Province

Fars

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71956-15878

Phone

+98 71 3832 3435

Email

adla@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Rajabzadeh

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Shiraz University of Medical Sciences

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71956-15878

Phone
+98 71 3832 3435

Email
adla@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Zahra Rajabzadeh

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

Street address
Ghasrodasht avenue

City
Shiraz

Province
Fars

Postal code
71956-15878

Phone
+98 71 3631 5271

Fax

Email
dr.zrajabzadeh@gmail.com

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
Yes - There is 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
Not applicable

Title and more details about the data/document
the main outcome information

When the data will become available and for how long
starting 6 months after the publication

To whom data/document is available
academic and industrial investigators

Under which criteria data/document could be used
academic and industrial investigators

From where data/document is obtainable
adla@sums.ac.ir

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

Comments