# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

26 May 2026

## Efficacy of Chlorhexidine 0/12% and 0/2 % Povidone-iodine mouth rinse on clinical characteristics of patients with COVID-19

## Protocol summary

**Study aim**
Determining the effect of using chlorhexidine 0/12% and Povidone-iodine 0.2% mouth rinse on clinical characteristics of patients with COVID-19

**Design**
Randomized, parallel clinical trial, phase 2-3 with block randomization

**Settings and conduct**
Patients with COVID-19 who referred to Beheshti Hospital in Kashan, are examined for oral health (based on Oral health assessment scale) are divided into two groups Healthy (Good And Moderate) and Unhealthy (Poor and Bad ) and are randomly divided into four groups: intervention (treatment with chlorhexidine 0/12 %, Povidone-iodine 0.2% ,Povidone-iodine 0.2% and chlorhexidine0/12% mouthwash) and control only do routine oral hygiene (toothbrush and floss). Patient are examined daily until discharge and their clinical and paraclinical information is recorded. their laboratory and clinical data are obtained from hospital database. Length of hospitalization , condition of ventilation and duration of one month survive (by call) after discharge are recorded. If patients have oral lesions, they will be treated.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria : possibility of involving to COVID-19; PaO2/FiO2 < 300 mm Hg or SpO2 < 93% in air ambient or need to oxygen supplementary for SpO2 in range of 94-98% or lung infiltration > 50%; consciousness of patient ; minimum 18 years old Exclusion criteria :Pregnancy; Immunodeficiency such as patient with Severe combined immune deficiency and HIV; Allergy to mouth rinse; Immunosuppressant drug consumer such as transplantation recipient patient; Dissatisfaction with participating in the study

**Intervention groups**
intervention groups :treatment with chlorhexidine 0/12% and Povidone-iodine 0.2% mouth rinse , treatment with chlorhexidine 0/12% mouth rinse, treatment with Povidone-iodine 0.2% mouth rinse

**Main outcome variables**
Xerostomia index, oral ulcers ,mouth redness changes, changes in taste

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200527047581N2**
Registration date: **2021-03-17, 1399/12/27**
Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**
Update count: **0**

**Registration date**
2021-03-17, 1399/12/27

**Registrant information**

**Name**
Elaheh Ghasemzadeh hosseini

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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+98 21 3389 1966

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-04-09, 1400/01/20

**Expected recruitment end date**
2021-07-11, 1400/04/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Efficacy of Chlorhexidine 0/12% and 0/2 % Povidone-iodine mouth rinse on clinical characteristics of patients with COVID-19

**Public title**
Efficacy of Chlorhexidine 0/12% and 0/2 % Povidone-iodine mouth rinse on clinical characteristics of patients with COVID-19
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
possibility of involving to COVID-19 PaO2/FiO2 < 300 mm Hg or SpO2 < 93% in air ambient or need to oxygen supplementary for SpO2 in range of 94-98% or lung infiltration > 50% consciousness of patient and to be able to complete letter of satisfaction minimum 18 years old
**Exclusion criteria:**
Pregnancy patient Immunodeficiency such as patient with Severe combined immune deficiency and HIV Allergy to mouth rinse Immunosuppressant drug consumer such as transplantation recipient Dissatisfaction with participating in the study
**Age**
From **18 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **180**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
block randomization / random allocation on 180 patients with COVID-19 Thus, in each of four groups : the intervention groups ( chlorhexidine , povidone-iodine , chlorhexidine and povidone-iodine) and control groups, 4 randomization blocks are allocated. It is worth mentioning that random sequences in the execution of 4 blocks will be performed by the researcher without using statistical software allocation concealment does not apply in this study.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Kashan University of Medical Sciences
**Street address**
Ghotb Ravandi Blvd
**City**
kashan
**Province**
Isfehan
**Postal code**
55578011
**Approval date**
2021-01-27, 1399/11/08
**Ethics committee reference number**
IR.KAUMS.REC.1399.044

## Health conditions studied

### 1

**Description of health condition studied**
COVID-19 associated severe respiratory syndrome
**ICD-10 code**
U07.1
**ICD-10 code description**
SARS-CoV-2

## Primary outcomes

### 1

**Description**
Duration of hospitalization
**Timepoint**
End of study
**Method of measurement**
Calculation

### 2

**Description**
Xerostomia
**Timepoint**
Daily during first day of hospitalization until 28 days
**Method of measurement**
percent (has/has not)

### 3

**Description**
Change of Taste sense
**Timepoint**
Daily during first day of hospitalization until 28days

**Method of measurement**
percent (has/has not)

**4**

**Description**
New oral erythematous lesion
**Timepoint**
Daily during first day of hospitalization until 28 days
**Method of measurement**
percent (has/has not)

**5**

**Description**
new oral ulcer
**Timepoint**
Daily during first day of hospitalization until 28 days
**Method of measurement**
percent (has/has not )

## Secondary outcomes

**1**

**Description**
Para clinical outcome(White blood cell count)
**Timepoint**
The first day and the last day of discharge
**Method of measurement**
cell number x 1000

**2**

**Description**
Para clinical outcome (blood potassium)
**Timepoint**
The first day and the last day of discharge
**Method of measurement**
milligrams per deciliter

**3**

**Description**
Para clinical outcome (blood magnesium)
**Timepoint**
The first day and the last day of discharge
**Method of measurement**
milligrams per deciliter

**4**

**Description**
Para clinical outcome (platelet count)
**Timepoint**
The first day and the last day of discharge
**Method of measurement**
cell number x 1000

**5**

**Description**
Para clinical outcome (C Reactive protein)
**Timepoint**
The first day and the last day of discharge
**Method of measurement**
milligrams per deciliter

**6**

**Description**
Para clinical outcome (CURB65)
**Timepoint**
The first day and the last day of discharge
**Method of measurement**
scale

**7**

**Description**
Para clinical outcome (Creatinine)
**Timepoint**
The first day and the last day of discharge
**Method of measurement**
milligrams per deciliter

**8**

**Description**
Para clinical outcome(Respiratory rate per minute)
**Timepoint**
The first day and the last day of discharge
**Method of measurement**
number of breath per minute

**9**

**Description**
Para clinical outcome(blood pressure)
**Timepoint**
The first day and the last day of discharge
**Method of measurement**
millimeter of mercury

**10**

**Description**
Para clinical outcome(Body temperature)
**Timepoint**
The first day and the last day of discharge
**Method of measurement**
centigrade

**11**

**Description**
Para clinical outcome (heart rate per minute)
**Timepoint**
The first day and the last day of discharge
**Method of measurement**
beats per minute

**12**

**Description**
Para clinical outcome (Blood Urea nitrogen)
**Timepoint**

The first day and the last day of discharge

**Method of measurement**

milligrams per deciliter

### 13

**Description**

Para clinical outcome (blood sodium )

**Timepoint**

The first day and the last day of discharge

**Method of measurement**

milligrams per deciliter

### 14

**Description**

Para clinical outcome (Blood glucose)

**Timepoint**

The first day and the last day of discharge

**Method of measurement**

milligrams per deciliter

### 15

**Description**

para clinical outcome (Hematocrit)

**Timepoint**

The first day and the last day of discharge

**Method of measurement**

percentage

### 16

**Description**

Para clinical outcome (Oxygen saturation)

**Timepoint**

The first day and the last day of discharge

**Method of measurement**

percentage

### 17

**Description**

para clinic outcome (erythrocyte sedimentation rate)

**Timepoint**

The first day and the last day of discharge

**Method of measurement**

millimeter

### 18

**Description**

Para clinic outcome (CT)

**Timepoint**

The first day

**Method of measurement**

number of focal of lung involvement

### 19

**Description**

Para clinic outcome (neutrophil)

**Timepoint**

The first day and the last day of discharge

**Method of measurement**

cell number x 1000

### 20

**Description**

Para clinic outcome (lymphocyte)

**Timepoint**

The first day and the last day of discharge

**Method of measurement**

cell number x 1000

### 21

**Description**

Para clinic outcome(mean corpuscular volume)

**Timepoint**

The first day and the last day of discharge

**Method of measurement**

femtoliter

### 22

**Description**

Para clinic outcome (hemoglobin)

**Timepoint**

The first day and the last day of discharge

**Method of measurement**

grams per deciliter

### 23

**Description**

para clinic outcome (AST)

**Timepoint**

The first day and the last day of discharge

**Method of measurement**

units per liter

### 24

**Description**

Para clinic outcome (ALT)

**Timepoint**

The first day and the last day of discharge

**Method of measurement**

units per liter

### 25

**Description**

Para clinic outcome (ALP)

**Timepoint**

The first day and the last day of discharge

**Method of measurement**

units per liter

## Intervention groups

### 1

**Description**

Intervention group: patients with a probable diagnosis of

COVID-19 will receive oral health care training by a nurse, including: tooth and tongue brush, cleaning dentures in people with dentures. Rinse chlorhexidine 0.12% mouthwash every 12 hours for one minute and Povidone-iodine 2% mouthwash every 6 hours 4 times a day for 2 minutes.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: patients with a probable diagnosis of COVID-19 will receive oral health care training by a nurse, including: tooth and tongue brush, cleaning dentures in people with dentures. Rinse chlorhexidine 0.12% mouthwash every 12 hours for one minute.

**Category**

Treatment - Drugs

**3**

**Description**

Intervention group: patients with a probable diagnosis of COVID-19 will receive oral health care training by a nurse, including: tooth and tongue brush, cleaning dentures in people with dentures. Rinse Povidone-iodine 2% mouthwash every 6 hours 4 times a day for 2 minutes.

**Category**

Treatment - Drugs

**4**

**Description**

Control group: patients with a probable diagnosis of COVID-19 will receive oral health care training by a nurse, including: tooth and tongue brush, cleaning dentures in people with dentures.

**Category**

N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Shahid Beheshti Hospital
**Full name of responsible person**
Dr.Mohammad Reza Sharif
**Street address**
Gotbe Ravandi Blvd.
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beheshtihospital@kaums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Kashan University of Medical Sciences
**Full name of responsible person**
Dr. Hamidreza Banafsheh
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research@kaums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
No

**Title of funding source**
Kashan 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**
Kashan University of Medical Sciences
**Full name of responsible person**
Elaheh GhasemzadehHosseini
**Position**
Assistant Professor
**Latest degree**
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**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
Not applicable
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
Not applicable
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable