Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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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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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?
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
Specialist
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