Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Efficacy of professional oral health care (POHC) and chlorhexidine and% 0/2 povidon Iodine mouth rinse on survival rate and clinical characteristics of patients with Covid-19

Protocol summary

Study aim

Efficacy of professional oral health care (POHC) and chlorhexidine and0/2 % povidon Iodine mouth rinse on survival rate and clinical and paraclinical characteristics of patients with Covid19

Design

Two arm parallel group randomised trial with block randomization on 200 patients

Settings and conduct

A clinical trial will be performed on 200 patients suspected of having 19 patients admitted to Taleghani Hospital in Ahvaz and Shaheed Beheshti in Kashan .Patients are examined for oral health then will divide to 4 groups according on Oral Health Scale: Good, Moderate ,Poor,Fair .Regarding oral health they will divide into two groups :healthy (patient with good and moderate scale) and Unhealthy (patient with poor and fair scale) . Patients are then randomly divided into two groups: training intervention and use of chlorhexidine and Betadine mouthwash) and control group.

Participants/Inclusion and exclusion criteria

Include criteria: 1. possibility of involving to Covid-19 2. PaO2/FiO2 < 300 mm Hg or SpO2 < 93% in air ambient or need to Oxygen supplementary for SpO2 to 94-98% or lung infiltration >50% 3.consciousnesses of patient and be able to complete letter satisfaction Exclude criteria: 1.Pregnancy 2.Allergy to mouth rinse 3.Immunodeficiency such as : Sever combined immuno deficiency and HIV 4. Immuno suppressant Drugs consumer such as : transplantation recipient patient 5.Dissatisfaction with participating in the study

Intervention groups

education of professional oral health care (POHC) and chlorhexidine and0/2 % povidon Iodine mouth rinse for intervention group and recommendation of routine oral hygiene for control group

Main outcome variables

survival rate,clinical outcome,para clinical outcom

General information

Reason for update

1. Failure to receive the IRCT code by the expected date;
2. The lack of feasibility regarding travel, procurement of materials, on-site presence in the ward, and accompaniment by ward nurses, given the COVID-19 conditions at the time.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200527047581N1**
Registration date: **2020-08-23, 1399/06/02**
Registration timing: **prospective**

Last update: **2026-08-26, 1405/06/04**
Update count: **1**

Registration date

2020-08-23, 1399/06/02

Registrant information

Name

Elaheh Ghasemzadeh hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3389 1966

Email address

ghasemzadeh-e@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-05, 1399/03/16

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

2020-09-23, 1399/07/02

Actual recruitment end date

2020-12-22, 1399/10/02

Trial completion date

2020-12-22, 1399/10/02

Scientific title

Efficacy of professional oral health care (POHC) and chlorhexidine and% 0/2 povidon Iodine mouth rinse on survival rate and clinical characteristics of patients with Covid-19

Public title

Effect of oral health care and mouth rinse in treatment of 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 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

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Actual sample size reached: **183**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization / random allocation on 200 patients with covid 19 Thus, in each of the intervention 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

2020-05-06, 1399/02/17

Ethics committee reference number

IR.KAUMS.REC.1399.015

Health conditions studied

1

Description of health condition studied

SARS-CoV-2 ãssociated SARI

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

mortality status

Timepoint

28 days after admit day

Method of measurement

percent (live/ dead)

3

Description

Xerostomia

Timepoint

Daily during first day of hospitalization until 28 days

Method of measurement
percent (has/has not)

4

Description
Change of Taste sens
Timepoint
Daily during first day of hospitalization until 28 days
Method of measurement
percent (has/has not)

5

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

6

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 decilitre

3

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

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 decilitre

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 decilitre

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
millimetre 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 decilitre

13

Description

para clinical outcome (blood nutriome)

Timepoint

The first day and the last day of discharge

Method of measurement

milligrams per decilitre

14

Description

para clinical outcome (Blood glucose)

Timepoint

The first day and the last day of discharge

Method of measurement

milligrams per decilitre

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

millimetre

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

femtolitre

22

Description

para clinic outcome(hemoglobin)

Timepoint

The first day and the last day of discharge

Method of measurement

grams per decilitre

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: .....
Category
Prevention

2

Description
Control group: .....
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shaheed Beheshti Hospital
Full name of responsible person
Dr.Mohammad Reza Sharif
Street address
Gotbe Ravandi
City
Kashan
Province
Isfehan
Postal code
8715981151
Phone
+98 31 5554 0026
Fax
+98 31 5554 8900
Email
beheshtihospital@kaums.ac.ir

2

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Soltan Ali Bahmani
Street address
Phase 2 of Padadshahr, in front of the police station 23
City
Khuzestan
Province
Khouzestan
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Email
Ahlam.tor.95@gmail.com

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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+98 31 5557 5057
Email
research@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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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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