# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 Jun 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**

**Acronym**

**IRCT registration information**

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

Last update: **2020-08-23, 1399/06/02**
Update count: **0**

**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**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**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**

**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 ássociated 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**
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+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
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Kashan University of Medical Sciences
**Full name of responsible person**
Dr. Hamidreza Banafsheh
**Street address**
Ghotb Ravandi
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kashan
**Province**
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**Fax**
+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
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**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