

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of oral care using Artificial saliva to control dry mouth in patients with COVID-19 under non-invasive mechanical ventilation: A quasi-experimental study

#### Protocol summary

##### Study aim

The effect of oral care using Artificial saliva to control dry mouth in patients with COVID-19 under non-invasive mechanical ventilation

##### Design

Clinical trial with control group, parallel groups, without blinding, non-randomised, phase 3 on 80 patients.

##### Settings and conduct

In Labbafinejad Hospital, the sampler will be present in the intensive care unit of COVID-19 patients. In addition to routine care, this hospital also uses artificial saliva 3 times a day. The other person will be present at Modares Hospital at the same time. In both hospitals, on the first day of patients' use of non-invasive mechanical ventilation, demographic information and the results of the initial assessment of patients' mouths will be recorded, then each patient will be examined daily for three days.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients admitted to the intensive care unit with COVID-19 (having a CT scan or positive PCR test), age over 18 years. Criteria for not entering: Patients taking salivary-lowering drugs or those with systemic glandular disease Saliva, patients with obvious oral lesions, pests.

##### Intervention groups

In both hospitals, on the first day of patients' use of non-invasive mechanical ventilation, demographic information and the results of the initial oral assessment of patients will be recorded, then each patient for Three days will be examined daily and the oral condition of patients in both hospitals will be evaluated. Examination and evaluation of patients's mouth, in 4 stages including (day zero: before the start of non-invasive mechanical ventilation, first day: one day after the use of non-invasive mechanical ventilation until the third day (3 days after the use of non-invasive mechanical

ventilation) Will be done.

##### Main outcome variables

Dry mouth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220223054107N1**

Registration date: **2022-02-25, 1400/12/06**

Registration timing: **prospective**

Last update: **2022-02-25, 1400/12/06**

Update count: **0**

##### Registration date

2022-02-25, 1400/12/06

##### Registrant information

##### Name

sorour khari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8879 2453

##### Email address

sorour.khari@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-01, 1400/12/10

##### Expected recruitment end date

2022-08-21, 1401/05/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of oral care using Artificial saliva to control dry mouth in patients with COVID-19 under non-invasive mechanical ventilation: A quasi-experimental study

**Public title**

The effect of oral care using Artificial saliva to control dry mouth in patients with COVID-19 under non-invasive mechanical ventilation: A quasi-experimental study

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients admitted to the intensive care unit with COVID-19 (having a CT scan or positive PCR test) under non-invasive mechanical ventilation age over 18 years  
Patients with similar mechanical ventilation settings

**Exclusion criteria:**

Patients taking drugs associated with decreased salivary function. Patients with obvious oral lesions, pest  
Pregnant patients

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****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**

Vice-Chancellor in Research Affairs - Shahid Beheshti  
University of Medical Sciences

**Street address**

Tehran, Velenjak, 7th Floor, Bldg No.2 SBUMS, Arabi

Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Approval date**

2022-02-06, 1400/11/17

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1400.1025

**Health conditions studied****1****Description of health condition studied**

COVID-19 patients

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

**Primary outcomes****1****Description**

Dry mouth

**Timepoint**

Examination and evaluation of patients' mouths in 4 stages including (day zero: before the start of non-invasive mechanical ventilation, first day: one day after the use of non-invasive mechanical ventilation until the third day (3 days after the use of non-invasive mechanical ventilation) .

**Method of measurement**

Beck Oral Assessment Scale (BOAS) Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control group: This group receives only routine care (Chlorhexidine mouthwash 0.2% and normal saline) .

**Category**

Prevention

**2****Description**

Intervention group: In this group, in addition to routine care (Chlorhexidine mouthwash 0.2% and normal saline), mucosamin synthetic saliva spray is also used 3 times a day for 3 days. Initially, on the first day of patients with COVID-19 use of non-invasive mechanical ventilation, demographic information and the results of the initial

oral assessment of patients will be recorded, then the patient's oral condition will be examined daily for three days. Examination and evaluation of patients's mouth, in 4 stages including (day zero: before the start of non-invasive mechanical ventilation, first day: one day after the use of non-invasive mechanical ventilation until the third day (3 days after the use of non-invasive mechanical ventilation) Will be done by the Oral Dryness Scale (BOAS).

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Labbafinezhad Hospital

##### Full name of responsible person

Dr. Mohammad Hossein Soltani

##### Street address

Tehran, 9th Boostan St.

##### City

Tehran

##### Province

Tehran

##### Postal code

1666663111

##### Phone

+98 21 23601

##### Email

labafinejad.hos@tamin.ir

### 2

#### Recruitment center

##### Name of recruitment center

Modarres Hospital

##### Full name of responsible person

Dr. Saeed Alipour Parsa

##### Street address

Kaj Sq., Sadat Abad St., Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1998734383

##### Phone

+98 21 2207 4087

##### Email

modarres@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr. Afshin Zarghi

##### Street address

Yaman St, Parvaneh St., Next to Taleghani Hospital, Chamran High Way, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 2243 9781

##### Email

Mpajouhesh@sbmu.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Sorour Khari

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

Valiasr St., Niayesh Highway Intersection, School of Midwifery Nursing Shahid Beheshti University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 8865 5366

##### Email

sorourkhari71@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ladan Sedighi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Valiasr St., Niayesh Highway Intersection, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 8865 5366

**Email**

l.sedighie@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Sorour Khari

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Valiasr St., Niayesh Highway Intersection, School of Midwifery Nursing Shahid Beheshti University of Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 8865 5366

**Fax****Email**

sorourkhari71@gmail.com

## 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**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available