

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