Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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
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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

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2

Recruitment center

Name of recruitment center
Modarres Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Afshin Zarghi

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

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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

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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
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