

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of oral hygiene protocol on dental plaque and gingival index in patients with Endotracheal tube hospitalized in intensive care unit

Protocol summary

Summary

The aim of this study is comparison the effect of oral health protocols and routine protocol on dental plaque and gingival index. In this study 70 intubated patients who admitted in ICU ward of Zanzan Ayatollah Mousavi Hospital, will be randomly divided into two groups. patients with age of 18-65 years old who were admitted in ICU Less than 12 hours will eligible to the study. The intervention group will be carried on the basis of the designed protocol. In the first and fourth days of hospitalization (two hours after the last use of mouthwash) in both groups the O'Leary tool for measuring plaque index, and the tool of MGI, the adjusted tool of Sylms and Lu, will be used. The control group will be under the routine care of hospital staff and the intervention group will be under the care based on the proposed protocol. The latter group will be under the care of four trained nurses as researcher's assistants. Before the implementation of the protocol to determine the frequency and procedure of protocol performing, the adjusted assessment tool of Boas will be used. This will be performed by the researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211189664N5**
Registration date: **2016-08-18, 1395/05/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-18, 1395/05/28

Registrant information

Name

Mitra Payami Bousari

Name of organization / entity

Zanzan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 24 3315 6962

Email address

payami@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zanzan University of Medical Sciences

Expected recruitment start date

2016-05-25, 1395/03/05

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral hygiene protocol on dental plaque and gingival index in patients with Endotracheal tube hospitalized in intensive care unit

Public title

Effect of implementing oral hygiene protocol on improving the dental plaque and gingival index in patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: males and females 18 to 65 years old having endotracheal tube through the mouth, admitted

to ICU less than 12 hours, having natural teeth, no teeth fracture, The absence of coagulopathy, non-pregnancy, Exclusion criteria: to discharge from the ICU or die before completing the study, no inclination to continue the study by the patient's custodian.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

coin tossing

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zanjan University of Medical Sciences

Street address

Central Chiefs Zanjan University of Medical Science,
The beginning of the Islamic Republic Boulevard,
Azadi Square, Zanjan

City

Zanjan

Postal code**Approval date**

2016-05-04, 1395/02/15

Ethics committee reference number

ZUMS.REC.1395.35

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

Dental plaque

ICD-10 code

K03.6

ICD-10 code description

Deposits [accretions] on teeth

2**Description of health condition studied**

gingival index

ICD-10 code

K05.0

ICD-10 code description

Acute gingivitis

3**Description of health condition studied**

Dental plaque

ICD-10 code

K02.1

ICD-10 code description

Caries of dentine

4**Description of health condition studied**

gingival index

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

5**Description of health condition studied**

gingival index

ICD-10 code

K05.4

ICD-10 code description

Periodontosis

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

Status Dental Plaque

Timepoint

Immediately before intervention and four days later

Method of measurement

O'Leary Index

2**Description**

Status Gingival

Timepoint

Immediately before intervention and four days later

Method of measurement

Loe & Sillness

Secondary outcomes

1

Description

oral health

Timepoint

Immediately before intervention and four days later

Method of measurement

BOAS and MPS check lists

Intervention groups

1

Description

Intervention group: Using 15 ml of Chlorhexidin mouthwash, Use a toothbrush and toothpaste, lubricating lips and wetting the patient's mouth based on Boas tool
Adjusted for 4 days

Category

Prevention

2

Description

Control group: Using 15 ml of Chlorhexidin mouthwash every 12 hours, for 4 days

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Mitra Payami Busari

Street address

Ayatollah Mousavi Hospital, Road Gavazng

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zanjan University of Medical Sciences

Full name of responsible person

Sograt Faghihzadeh

Street address

Zanjan University of Medical Sciences, Azadi Square

City

Zanjan

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice chancellor for research, Zanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Ali ghaempanah

Position

MSc

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery

City

Zanjan

Postal code

4515789589

Phone

+98 24 3314 8300

Fax

Email

alighaempanah511@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Science

Full name of responsible person

Mitra payami Bousari

Position

PhD

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery

City

Zanjan

Postal code

4515789589

Phone

+98 24 3314 8300

Fax

Email

payami@zums.ac.ir

Web page address

+98 33148319

Person responsible for updating data

Email

payamizums.ac.ir

Web page address

Contact

Name of organization / entity

Zanjan University of Medical Science

Full name of responsible person

Mitra Payami Busari

Position

PhD

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery

City

Zanjan

Postal code

4515789589

Phone

+98 24 3314 8300

Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty