Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 Zanjan 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 Sylns 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

Zanjan 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, Zanjan 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 Cholorhexidin 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 Cholorhexidin 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

Person responsible for updating data

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
+98 33148319

Email
payamizums.ac.ir

Web page address

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