Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Barrow Oral Care Protocol on Oral Health in Patients Undergoing Mechanical Ventilation Admitted in the Intensive Care Unit

Protocol summary

Study aim

To investigate the effect of Barrow Oral Care Protocol on Oral Health in Patients Receiving Mechanical Ventilation Admitted in the Intensive Care Unit

Design

A double-blind clinical trial was performed on 90 patients admitted to intensive care units in 2018-19 using block randomization method in both control and intervention groups.

Settings and conduct

This study was a triple-blind clinical trial which was performed on 90 patients admitted to intensive care units of Fatemi hospital in Ardabil, Iran. Except for the researcher and clinical caregivers who were aware of the method of care, evaluator nurse, guidance counselor, statistics consultant and patient were unaware of the type of care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients admitted to intensive care unit (ICU), Patients Receiving Mechanical Ventilation, and aged 15 to 45 years. Non-inclusion criteria: Dissatisfaction of the patient's legal guardian, patients undergoing artificial ventilation with tracheostomy, patients with oral trauma.

Intervention groups

Control group: mouthwash of patients with 0.2% chlorhexidine mouthwash three times daily for 5 days. Intervention group: For these patients, a combined oral care protocol based on Barrow's Modified Protocol for 5 days consisted of washing the tongue with tongue scraping, brushing with toothbrush and a thin layer of petroleum jelly applied to lips twice، Oral care mucosal care includes rinsing the mouth with a 0.2 chlorhexidine-soaked swab and moistening the oral cavity with Mucosamine oral spray.

Main outcome variables

Oral health status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180915041041N1**
Registration date: **2020-05-01, 1399/02/12**
Registration timing: **retrospective**

Last update: **2020-05-01, 1399/02/12**
Update count: **0**

Registration date

2020-05-01, 1399/02/12

Registrant information

Name

Robab Javanmard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3344 5805

Email address

javanmard_1354@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

2018-11-06, 1397/08/15

Actual recruitment end date

2019-06-20, 1398/03/30

Trial completion date

2019-06-25, 1398/04/04

Scientific title

The effect of Barrow Oral Care Protocol on Oral Health in Patients Undergoing Mechanical Ventilation Admitted in the Intensive Care Unit

Public title

The effect of Barrow Oral Care Protocol on Oral Health in Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients admitted to intensive care units (ICU) Patients undergoing mechanical ventilation. Patients aged 15 to 45 years

Exclusion criteria:

Dissatisfaction of the patient's legal guardian Patients with facial trauma Having previous underlying disease such as diabetes, asthma, kidney failure, heart, liver, Patients undergoing chemotherapy or treatment with corticosteroids Patients previously undergoing transplantation of one of the vital organs of the body, such as the heart, kidney, liver and pancreas. Patients treated with Immunosuppressants Patients with blood diseases such as hemophilia,Thalassemia, leukemia, , platelet deficiency or any of the blood cells Patients with severe infection and sepsis Patients with scalp and neck burns

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization. To randomly assign patients to two, 6 blocks of size 4 were used. In this randomization, letter A was used to call routine group and letter B was used to name patients in the intervention group. Each block contains 4 alternatives. Block 1: A A B B Block 2: A B A B Block 3: A B B A Block 4: B B A A Block 5: B A B A Block 6: B A A B Then, with six presumptive blocks, six numbers (1 to 6) were selected. Based on sample size of 90 patients, 23 blocks were randomly selected until reaching sample size of 90 patients. Finally, 45 patients were allocated to each groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Because the randomization was performed by the original researcher, only the researcher was aware of the patients' care methods according to the relevant code, and the rest of the people, including the participating patient or the patient's legal guardian, only agreed to get care and were unaware of the type of care. The patient's oral assessor evaluated and recorded the patient's oral health only on a daily basis in a form that included a table of clinical oral health assessment tools used for both intervention and control groups and did not know the type of care in each group. And the counselor is also unaware of how to code for patients They were.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Student Research Committee, Ardabil University of Medical Sciences, Above Shorabil Lake, Daneshgah street, Ardabil

City

Ardabil

Province

Ardabil

Postal code

5618953141

Approval date

2018-08-26, 1397/06/04

Ethics committee reference number

IR.ARUMS.REC.1397.054

Health conditions studied

1

Description of health condition studied

Respiratory failure

ICD-10 code

J96

ICD-10 code description

Respiratory failure, not elsewhere classified

Primary outcomes

1

Description

Oral health status

Timepoint

Oral Health Assessment at the beginning of the study,

daily and completion of the study.

Method of measurement

Scale BOE(Bed side Oral Exame)

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group":in this group, care was started based on Barrow Oral Care Protocol and continued for 5 consecutive days. The protocol suggests three types of oral care based on the patient's oral health assessment score based on the clinical assessment of oral health (BOE) during admission.For patients with good oral health with an oral health score (BOE 8-10), the basic protocol of oral care includes washing the tongue using saline, brushing with a toothbrush and toothpaste, and rubbing a thin layer of Vaseline ointment. It is applied on the lips every 12 hours a day. In patients with moderate oral health status with oral and dental health score (BOE 11—14), in addition to basic oral care according to the main protocol, oral mucosal care, which includes rinsing the mouth with a wet swab with chlorhexidine chloride solution 0.2% and using Mucosamine moisturizing spray was added to the patient's oral care every 4 hours, and in patients with poor oral health status with an oral health score (15 to 24), in addition to oral care every 12 hours, oral mucosal care was evaluated every two hours. At the beginning of the patient's daily admission, the patient's oral and dental health status was monitored and evaluated by the evaluator, and the nurse who cared for the patient's mouth and teeth took care of the patient based on the new score.

Category

Treatment - Devices

2

Description

Control group: In this group, after determining and recording the patient's oral health score based on the clinical oral health assessment tool (BOE) on the first day of admission, taking care of the patient's oral health, according to the routines of the ward including rinsing the patient's mouth in each shift using gas soaked in solution Chlorhexidine 0.2%, was started by the patient's nurse and continued for 5 consecutive days. At the beginning of the patient's admission and every day after that, the patient's oral health status was checked by the evaluator, and the nurse in charge of the patient's care performed the patient's oral health care according to the routines of ward without attention to the patient's oral health score.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi hospital

Full name of responsible person

Dr. Mommad Vakili

Street address

Fatemi Educational Center, not reaching Shariati Square, Imam Khomeini Street, Sarein Station,Ardabil

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

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Web page address

http://www.arums.ac.ir/vcresearch/fa

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

60

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

Ardabil University of Medical Sciences

Full name of responsible person

Robab Javanmard

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

Nursery

Street address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Thesis

When the data will become available and for how long

Always

To whom data/document is available

researchers

Under which criteria data/document could be used

For use in research

From where data/document is obtainable

Ardabil University of Medical Sciences

What processes are involved for a request to access data/document

Written Request

Comments