Clinical Trial Protocol
Iranian Registry of Clinical Trials
14 Dec 2021

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
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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 A B 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

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Dr. Shahab Bahloli

Street address
Vice Chancellor for Research and Technology, headquarters building of Ardabil University of Medical Sciences, at the end of Daneshgah street, Ardabil

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Province
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Email
research@arums.ac.ir

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
**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 scientific inquiries**

**Contact**

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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**