Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effectivness of toothbrush and chlorhexidine solution and calendula officinalis extracts in preventing oral lesions in intubated patients

Protocol summary

Study aim

Comparison of The effectivnes of using the toothbrush and chlorhexidine solution and Calendola solution in the prevention of oral cavity lesions in patients intubated in intensive care units

Design

The clinical trial has three groups of parallel, community-based, and pragmatic. Each group has 19 samples. Blind two-way is to random allocation method.

Settings and conduct

After obtaining the necessary permits, the research is done in the intubated patients of Sabzevar's intensive care units. The double-blind study is blind, the assessor and the consulor are blinded to the bias. Trials are performed at intervals of every 12 hours in three groups. The assessment is recorded at the reception and on the fourth and seventh day by the BOAS tool.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Obtain informed consent from the legal representative of the patient, intubated patient and in the range of 18 to 65 years old. Having at least 20 healthy teeth, no illness and severe damage to the oral cavity, no coagulation problems and hepatitis B disease, history of HIV and allergic history, no symptoms of aspiration, lack of cover and parcel, dentures and other orthodontic instruments, score greater than 5 The basis of BOAS, lack of pregnancy and lactation in women. Exit criteria: Dissatisfied with the legal representative of the patient to continue cooperation, withdrawal of the tracheal tube, observation of aspiration apparent

Intervention groups

The intervention group 1 consists of intubated patients in the intensive care unit who received: oral toothbrushing ,and control group 2 chlorhexidine solution with toothbrush, and intervention group 3 brush with calendola.

Main outcome variables

The main outcome is the primary outcome of oral cavity health based on the Boas instrument and the secondary outcome variable is the complications of oral cavity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180512039625N1**
Registration date: **2019-01-16, 1397/10/26**
Registration timing: **retrospective**

Last update: **2019-01-16, 1397/10/26**
Update count: **0**

Registration date

2019-01-16, 1397/10/26

Registrant information

Name

Hosein Norozibami

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectivness of toothbrush and chlorhexidine solution and calendula officinalis extracts in preventing oral lesions in intubated patients

Public title
Comparison of effectivness of toothbrush and chlorhexidine solution and calendula officinalis extracts in preventing oral lesions
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent of the legal representative The patient is Intubated during the study (oral endotracheal tube). Having age between 18 to 65 years Have at least 20 teeth No severe shaking and ulcers in the mouth No history of hepatitis B and HIV, according to the doctor and see the test Absence of signs of aspiration According to the doctor and see no problem coagulation tests Have not doing dentures No history of allergic lesions and bleeding and periodontal disease in the mouth Lack of oral lesions and oral & maxillofacial fractures or anatomic abnormalities The absence of crowns and dentures and partial plates and other orthodontic devices Lack of grade 5 and less on the tools BOAS Lack of pregnancy and lactation in women
Exclusion criteria:
Legal representative of patient dissatisfaction continued cooperation Out of the endotracheal tube Find aspiration revealed The incidence of allergic reactions
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **57**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method is simple type using a random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to avoid bias, the person who carries out the intervention (special care nurse with 22 years of work experience) and the evaluator are different, the assessor is blind about the type of mouthwash procedure. In this study, a statistic counselor is also required to prevent blind bias. Statisticians and counselors are involved with coding patients in this study.
Placebo
Not used
Assignment
Parallel
Other design features
Each sample monitoring period is a week to study the effect of microbial resistance chlorhexidine solution is possible. Marigold solution is used as a mouthwash solution.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences
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Approval date
2018-05-09, 1397/02/19
Ethics committee reference number
IR.MEDSAB.REC.1397.004

Health conditions studied

1

Description of health condition studied
Mouthwash and prevention of oral cavity lesions
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Oral health
Timepoint
Admission, fourth and seventh day of hospitalization
Method of measurement
Beck Oral Assessment Score

Secondary outcomes

1

Description
diseases of lip
Timepoint
Admission, fourth and seventh day of hospitalization
Method of measurement
Beck Oral Assessment Score

2

Description
diseases of oral mucosa
Timepoint
Beck Oral Assessment Score
Method of measurement
Admission, fourth and seventh day of hospitalization

3

Description
Diseases of tongue
Timepoint
Admission, fourth and seventh day of hospitalization
Method of measurement
Beck Oral Assessment Score

4

Description
periodontal diseases
Timepoint
Admission, fourth and seventh day of hospitalization
Method of measurement
Beck Oral Assessment Score

Intervention groups

1

Description
The first intervention group (toothbrush group): in case of lack of contraindication, the patient's bed head is placed at a 30-degree angle and suction of the oral cavity is performed, if necessary. In addition, the sterilized mouthwash set is opened, and all internal and external surfaces of the teeth, gums, tongue, palate, and the trachea, with the exception of lips, are cleaned with a soft toothbrush for three-four minutes. In the end, the oral cavity is washed with 0.9% normal saline solution.
Category
Prevention

2

Description
The second intervention group (toothbrush-calendula group): in case of lack of contraindication, the patient's bed head is placed at a 30-degree angle and suction of the oral cavity is performed, if necessary. The dressing set is opened, and the oral cavity is washed with normal saline. All internal and external surfaces of the teeth, gums, tongue, palate, and the trachea, with the exception of lips, are cleaned with a soft toothbrush for three-four minutes. In the end, the oral cavity was washed with forceps and cotton impregnated with 0.2%calendula solution (five cc) for two and a half minutes. Afterwards, the oral cavity was washed with 0.9% normal saline and suctioned one more time. The oral cavity health was recorded upon admission and at the end of the fourth and seventh days.
Category
Prevention

3

Description
Control group (toothbrush-chlorhexidine): after performing the steps of the toothbrush group, five cc of 0.2% chlorhexidine solution (Mahsa Company) is poured into the sterile receiver. Afterwards, all parts of the oral cavity are washed with forceps and a cotton ball impregnated with 0.2% chlorhexidine solution for two minutes. Following that, we wait up to 30 seconds so that the antimicrobial properties of chlorhexidine could appear. In the final stage, the oral cavity is washed with 0.9% normal saline and is then suctioned. The oral health is recorded by BOAS upon admission, as well as at the end of the fourth and seventh days.
Category
Prevention

Recruitment centers

1

Recruitment center
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Martyr Beheshti Hospital in Sabzevar
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Sponsors / Funding sources

1

Sponsor
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Web page address
http://fa.irct.ir/user/trial/31602/update/sponsor
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments

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