

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Investigating the effect of pomegranate skin mouthwash on oral hygiene and bacterial colonization of oral and tracheal intubated patients admitted to the intensive care units(ICUs)

Protocol summary

Study aim

Determining the effect of pomegranate peel extract

Design

Clinical trial with a control group, with parallel groups, single-blind, randomized, phase 2 on 80 patients. A table of random numbers was used for randomization

Settings and conduct

After making the necessary arrangements, the researcher will go to the intensive care units (ICU) of the teaching hospitals of Zahedan University of Medical Sciences. The 80 anesthetized patients hospitalized in the intensive care units will be divided into two intervention groups (40 people) and control groups (40 people). Evaluation of oral and dental health It will be measured using Beck's assessment scale (BOAS) and oral mucosal plaque score (MPS). Mouth care and washing in the patients of the intervention group using 0.2% chlorhexidine mouthwash and 0.2% pomegranate peel extract by the researcher and in the control group patients by the researcher according to the routine of the ICU department using 0.2% chlorhexidine mouthwash and mouthwashes in both groups twice a day It is used for patients with an interval of 12 hours and for 4 days. In order to determine the relationship between the growth rate of bacterial colonization in the mouth and tracheal tube in patients using chlorhexidine mouthwash and pomegranate peel extract, the culture will be sent to the laboratory on the first and fourth day.

Participants/Inclusion and exclusion criteria

Patients with a tracheal tube and a level of consciousness of 3 to 7 on the GCS scale Age 18 to 65 years

Intervention groups

The intervention group of mouthwash with pomegranate peel extract and the control group of chlorhexidine mouthwash

Main outcome variables

Bacterial colonization rate of tracheal tube of intubated patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230513058170N1**

Registration date: **2023-06-20, 1402/03/30**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-20, 1402/03/30**

Update count: **0**

Registration date

2023-06-20, 1402/03/30

Registrant information

Name

Marzieh Saravani Pak

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 54 3341 3973

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of pomegranate skin mouthwash on oral hygiene and bacterial colonization of oral and tracheal intubated patients admitted to the intensive care units(ICUs)

Public title
Investigating the effect of pomegranate skin mouthwash on oral hygiene and bacterial colonization of oral and tracheal intubated patients admitted to the intensive care units(ICUs)

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Intubated patients admitted to the special care department of teaching hospitals in Zahedan - Patients with a tracheal tube and a level of consciousness of 3 to 7 on the GCS scale 2- Age 18 to 65 years 3- 24 hours have passed since the admission or hospitalization of the patient 4- Having natural teeth in the patient 5- Not having a history of allergy to pomegranate 6- Absence of a specific lesion in the mouth 7- The patient should not have radiotherapy experience 8- Willingness of the patient's legal guardian to continue participating in the study 9- Obtaining oral health evaluation checklist score less than 16.
Exclusion criteria:
- Airway damage during intubation 2- Pneumonia as an inpatient diagnosis 3- History of allergy to used mouthwash, asthma, allergic rhinitis and skin inflammation 4- Signs of sensitivity to mouthwash, such as redness, urticaria, and sores inside the mouth 5- Transfer of the patient from ICU or his death before the completion of the research

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

Gender
Both

Phase
1-2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
More than 1 sample in each individual
Number of samples in each individual: **40**
The sample size was estimated with 80% power and 95% confidence level (significance level 0.05) based on the following formula, 40 people in each group and 80 people in total

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling is based on the entry criteria and is selected in an available manner, and then the random number table

will be used for the random allocation of patients in such a way that for each person from the sample, a point will be determined on the random number table using a pen tip, and then We move from right to left and a number will be selected from the table of random numbers. If even and zero digits are obtained, the person will be in the intervention group, and if odd numbers are obtained, the person will be placed in the control group

Blinding (investigator's opinion)

Single blinded

Blinding description

Single-blind clinical trial - in such a way that blinding will be done for the laboratory expert , for this purpose, the samples collected by the researcher will be provided to the laboratory in the same containers with the same label and code, and the laboratory official will not be aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

Zahedan, 62 Jam Jam St., Milan II, on the right side of the third door

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9814745413

Approval date

2023-05-14, 1402/02/24

Ethics committee reference number

IR.ZAUMS.REC.1402.056

Health conditions studied

1

Description of health condition studied

Investigating the effect of pomegranate peel extract mouthwash on oral hygiene

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The bacterial colonization status of the tracheal tube of intubated patients

Timepoint

on the first day (before admission of patients) and on the fourth day in the ICU department

Method of measurement

Beck's measurement scale - oral mucosal plaque score - culture from Score obtained from the scale (MPS) = 2-4 a unacceptable MPS = 7-8 weak, the score received every day on the scale (BOAS). Number 5 no disorder, 6-10 mild disorder, 11-15 moderate disorder, 16-20 severe disorder. Cultivation on the first day (before admission of patients) and the fourth day in the ICU department mouth and tracheal tube

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group-preparation of pomegranate peel extract from Adonisgol Daru Company-Tehran, has an international approval and certificate. Pomegranate peel extract with a concentration of 0.2% is administered twice a day at an interval of 12 hours (9-21) for four days, before the intervention. The entire surface of the mouth, gums, tongue, pharynx, and tooth surfaces is carefully brushed with a soft children's toothbrush, and the remaining secretions in the throat and mouth are suctioned with a sterile green Nalaton catheter in less than 30 seconds. . The whole process of cleaning the mouth and washing takes 6 minutes.

Category

Prevention

2

Description

Control group: chlorhexidine mouthwash 0.2% - according to the routine of the ICU department using 0.2% chlorhexidine mouthwash, which is done twice a day every 12 hours (9-21) for four days, before the intervention. The entire surface of the mouth, gums, tongue, pharynx, and tooth surfaces is carefully brushed with a soft children's toothbrush, and the remaining secretions in the throat and mouth are suctioned with a sterile green Nalaton catheter in less than 30 seconds. . The whole process of cleaning the mouth and washing takes 6 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Teaching hospitals of Zahedan University of Medical Sciences

Full name of responsible person

Dr. Mehdi Rizvani Amin

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Behdasht Street-Mashahir Bivd-Zahedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Marzieh Saravani Pak

Position

Special care master nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available