

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of green tea extract on oral lesions in intubated patients admitted in the ICU

Protocol summary

Summary

The aim of this study is determining the effect of green tea extract on oral lesions in intubated patients admitted in the ICU . In this study 50 intubated patients who are admitted in ICU ward of Sabzevar vasei Hospital, will be randomly divided into two groups. Technique, timing and frequency of mouthwash application is similar in both groups. In the intervention group,10 ml chlorhexidine solution was used and after 1 hour green tea extract was used. This action is done every 8 hours during 4 days. Control group members wash their mouths with 10ml(Zero point two percent) chlorhexidine solution. This action is also done every 8 hours for 2 minutes during 4 days for control group. patients with age of 18-65 years old who are admitted in ICU Less than 6 hours will be eligible to the study. Transferring from ICU or death before the completion of intervention; allergy to mouthwash; history or current chronic or immune system diseases are exclusion criteria. During the study the mouth is checked three times a day before mouth intervention for four days, the patient's mouth is checked with Boas and Mucos plaque score(MPS) and those features are recorded in the checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042127513N1**

Registration date: **2016-06-15, 1395/03/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-15, 1395/03/26

Registrant information

Name

Mehdi Farzami

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research of Sabzevar University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-06-19, 1395/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of green tea extract on oral lesions in intubated patients admitted in the ICU

Public title

The effect of green tea extract on oral lesions

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Having oral endotracheal tube; being 18-65 years old ;The absence of wound; infection and oral trauma; Not having diseases like hepatitis B and HIV; Not having any symptoms or antecedent of aspiration; serious problems and artificial teeth. Exclusion criteria:

death at the time of the study; Separation from mechanical ventilation at the time of the study; View apparent aspiration; existence of allergic reactions and restrictions on procedures and aspiration risk.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this double blind randomized clinical trial samples in the two groups will be labeled by letters A, B. For randomization of the patients, random permutation of blocks was used. In this method, there were four patients in each block (2 chlorhexidine and 2 green tea). Then blocks were chosen randomly and the researcher who measures the implications of the study is unaware of the intervention groups. Patients are also blind as they are unconscious at the time of intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, next to the Asian road, Gonabad, Iran

City

Gonabad

Postal code

Approval date

2015-06-24, 1394/04/03

Ethics committee reference number

IR.GMU.REC.1394.26

Health conditions studied

1

Description of health condition studied

Gingivitis

ICD-10 code

k05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes

1

Description

oral health

Timepoint

Daily for 4 days

Method of measurement

Beck Oral Assessment Scale and Mucosal Plaque Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After approving of the study by Ethics committee of Gonabad University of medical sciences and completing the written consent forms by all participants in the study, patients are divided randomly into two equal groups: 25 patients in intervention and 25 in control group. In the intervention group, chlorhexidine solution was used and after one hour 10% green tea extract was used. This action is done every 8 hours during 4 days.

Category

N/A

2

Description

Control group: control group members wash their mouth with 0.2% (zero point two percent) chlorhexidine solution. This action is also done every 8 hours for 2 minutes during 4 days but for control group. Also, the observation of mouth is done by BOAS and MPS every 8 hours before utilizing a mouthwash (before washing mouth by chlorhexidine solution). Then, we record it in a checklist.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Vaseei Hospital

Full name of responsible person

Mehdi Farzami

Street addressvaseei Hospital, Keshavarz Blvd.
Sabzevar, Khorasan Razavi**City**

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2**Recruitment center****Name of recruitment center**

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Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice chancellor for Research of Sabzevar University of
Medical Sciences**Full name of responsible person**

Ali Mohammadpoor

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asian road, gonabad, iran**City**

Gonabad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice chancellor for Research of Sabzevar 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**

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Position

Student of MSc Nursing

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Tahereh baloochi bidokhti

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MSc./Member of Faculty

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empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty