

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The effect of oral moisturizing gel containing aloe vera and peppermint oil on Xerostomia and Mucosal-Plaque in intubate patients in ICU

Protocol summary

Summary

Objectives: Identify the effect of oral moisturizing gel containing aloe vera and peppermint oil on Xerostomia and Mucosal-Plaque in intensive care unit patients
Design: a triple blind randomized clinical trial. **Setting and conduct:** The eligible patients who will admitted to intensive care unit of Amin Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** age range of 18–65 years; no chronic disease; being intubated during the study period ; Less than 12 hours Intensive care unit length of stay . **Exclusion criteria:** being discharged from ICU; patient’s death; **Intervention group:** Using topical oral moisturizing gel containing aloe vera and peppermint oil twice a daily(Every 12 hours) apply 10 gr for 7 days. **Control group:** Using topical placebo twice a daily(Every 12 hours) apply 10 gr for 7 days **Primary outcome:** Assessing xerostomia before and after treatment through Challacombe Scale and Assessing mucosal-plaque formation before and after treatment through mucosal-plaque Score. **Secondary outcome:** Assessing local reactions such as hives, or redness after treatment through physical examination. **Randomization:** The patients will be randomly assigned to intervention and control groups using block randomization. **Blinding:** Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120331200N1**

Registration date: **2017-02-03, 1395/11/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-03, 1395/11/15

Registrant information

Name

Vajihe Atashi

Name of organization / entity

Nursing Faculty of Isfahan University

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral moisturizing gel containing aloe vera and peppermint oil on Xerostomia and Mucosal-Plaque in intubate patients in ICU

Public title

The effect of oral moisturizing gel on dry and mucous plaque formation in intubated patients admitted to a special section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age range of 18-65 years: no chronic disease: being intubated during the study period: Less than 12 hours Intensive care unit length of stay exclusion criteria: being discharged from ICU: patient's death

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar-Jerib Ave., Isfahan, Iran,

City

Isfahan

Postal code

Approval date

2016-12-21, 1395/10/01

Ethics committee reference number

IR.MUI.REC.1395.2.141

Health conditions studied

1

Description of health condition studied

Xerostomia and Mucosal-Plaque in intubate patients in ICU

ICD-10 code

K00-K93

ICD-10 code description

Diseases of oral cavity, salivary glands and jaws

Primary outcomes

1

Description

Xerostomia

Timepoint

before and after

Method of measurement

Challacombe Scale

2

Description

Mucosal-Plaque

Timepoint

before and after

Method of measurement

mucosal-plaque index

Secondary outcomes

1

Description

Assessing local reactions such as hives, or redness

Timepoint

after treatment

Method of measurement

through physical examination

Intervention groups

1

Description

Intervention group: Using topical oral moisturizing gel containing aloe vera and peppermint oil twice a daily(Every 12 hours) apply 10 gr for 7 days

Category

Treatment - Drugs

2

Description

Control group: Using topical placebo twice a daily(Every 12 hours) apply 10 gr for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Vajihe Atashi

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Isfahan University of Medical Sciences, Hezar-Jerib Ave, Isfahan, IR Iran

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Isfahan

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Isfahan University of Medical Science

Full name of responsible person

Nursing and Midwifery Research Center

Street address

Nursing and Midwifery Research Center, Nursing and Midwifery school, Isfahan University of Medical Science

City

Isfahan

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

Yes

Title of funding source

Isfahan University of Medical Science

Proportion provided by this source**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

2**Sponsor****Name of organization / entity**

Barij Essence Company

Full name of responsible person

Dr Reza Bekhradi

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mashhad ardehal, kashan

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kashan

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

Yes

Title of funding source

Barij Essence Company

Proportion provided by this source**Public or private sector**

empty

Domestic or foreign origin

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Nursing and Midwifery school

Full name of responsible person

Vajihe Atashi

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty