

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Investigating the effect of essential oil of thyme on oral microbial burden in mechanical ventilated ICU patients.

Protocol summary

Study aim

Investigating the effect of essential oil of the thyme on oral microbial burden in mechanical ventilated ICU patients

Design

A clinical trial with a control group with double-blind, randomized parallel groups

Settings and conduct

Mouthwash was used in all three groups of patients in mouth , gums , pharynx and teeth for 6 minutes. at the end , the solution is removed from the patient 's mouth by suctioning. the duration of the intervention will be the same in 3 groups and patient's position will be supine during the intervention. Additionally, repeated washing of hands and putting the sterile gloves before and after mouthwashes will be performed.

Participants/Inclusion and exclusion criteria

The participants in the study included all patients under mechanical ventilation admitted to the intensive care unit. Inclusion criteria: The patient is under mechanical ventilation in the intensive care unit Patients who do not have a inhibition for mouthwash. Exclusion criteria: Extenuation of the patient based on physician order during the study Patient's death during the study Patients diagnosed with brain death History of allergy to various compounds of thyme and mint Discharge of the patient from the intensive care unit

Intervention groups

Group 1: Mouthwash group with Thyme essential oil. The mouthwash used by Thyme Essential Oil from Barij Essen in the form of Glycoid10% solution is used Group 2: Mouthwashes with chlorohexidine 0.2% of Iran's Healthcare Company. The third group is the control group, in which the patients will use normal saline for mouth and throat washing.

Main outcome variables

The variable of the main outcome is oral microbial load that will be evaluated before and after the mouthwash.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100124003146N6**

Registration date: **2019-03-10, 1397/12/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-10, 1397/12/19**

Update count: **0**

Registration date

2019-03-10, 1397/12/19

Registrant information

Name

Ismail Azizi-Fini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

azizi-es@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of essential oil of thyme on oral microbial burden in mechanical ventilated ICU patients.

Public title

Investigating the effect of essential oil of thyme on oral microbial burden in mechanical ventilated ICU patients.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All the patients under the mechanical ventilation in intensive care units

Exclusion criteria:

Patients with no prohibition for mouthwash Patients with no sensitivity to thyme

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with inclusion criteria were randomly divided into three groups. Equal number of sample was allocated to each group using a randomized block method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Because participating patients have low level of consciousness and are ventilated, are not aware of the type of intervention (mouthwash) and are blind. On the other hand, the person who analyzes the culture is not aware of the type of mouthwash used.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

Street address

5th kilometer Qotb Ravandi blouvar

City

kashan

Province

Isfahan

Postal code

8715981151

Approval date

2019-01-21, 1397/11/01

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1397.050

Health conditions studied**1****Description of health condition studied**

oral thrush

ICD-10 code

B37.0

ICD-10 code description

Candidal stomatitis

Primary outcomes**1****Description**

oral microbial load

Timepoint

before using mouthwash and seven days after the intervention

Method of measurement

oral culture

Secondary outcomes**1****Description**

anti bio-gram

Timepoint

before and seven days after intervention

Method of measurement

sample of oral culture

Intervention groups**1****Description**

intervention group1: Mouthwash group with Thyme essential oil. The mouthwash, which is made by Barij essence company is made up of 10% glycidic solution, will be used twice a day (morning and night) for patients. So that the entire level of the mouth, gums, pharynx and tooth surfaces are swabbed for 6 minutes with 5 cc of solution. At the end of the mouthwash, the solution is removed from the mouth by suction (a sterile catheter without previous use).

Category

Treatment - Drugs

2

Description

Intervention group2: Mouthwash group with chlorohexidine 0.2% of Iran's Health Generation Company. So that the entire level of the mouth, gums, pharynx and tooth surfaces are swabbed for 6 minutes with 5 cc of solution. At the end of the mouthwash, the solution is removed from the mouth by suction (a sterile catheter without previous use).

Category

Treatment - Drugs

3

Description

Control group: The normal saline will be used. So that, the entire level of the mouth, gums, pharynx and tooth surfaces are swabbed for 6 minutes with 5 cc of solution. At the end of the mouthwash, the solution is removed from the mouth by suction (a sterile catheter without previous use).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital of kashan

Full name of responsible person

Dr Mohammadreza Fazel

Street address

5th kilometer Qotb Ravandi Blouvar. Parastar blouvar

City

kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0026

Fax

Email

zahra31260@gmail.com

Web page address

<http://beheshti.kaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Hamidreza Banafshe

Street address

5th Kilometer Qotb Ravandi. Kashan university of medical sciences

City

kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0021

Email

zahra31260@gmail.com

Web page address

<http://kaums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Dr Esmail Azizi-Fini

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

5Th Kilometer Qotb Ravandi blouvar. kashan university of medical sciences

City

kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0021

Email

azizi-es@kaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Esmail Azizi-Fini

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

5th kilometer Qotb Ravandi Blouvar

City

kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0021

Email

azizi-es@kaums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr Esmail Aziz-Fini

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

5th kilometer Qotb Ravandi Blouvar

City

kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0021

Email

azizi-es@kaums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

the results related to the main outcome will be distributed.

When the data will become available and for how long

after the publication of the article

To whom data/document is available

all people

Under which criteria data/document could be used

data will be confidential

From where data/document is obtainable

azizi-es@kaums.ac.ir

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

the process will be announced later.

Comments