

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

A Comparative effectiveness of honey 12.5% and chlorhexidine 0.2% mouthwash on the oropharyngeal bacterial colonization in mechanically ventilated Patients in ICU: A randomized control trial

Protocol summary

Summary

Objectives: The aim of this study is to compare the effect of honey 12.5% and chlorhexidine 0.2% mouthwashes to reduce the oropharyngeal bacterial colonization in mechanically ventilated patients in ICU. **Design:** This study is a phase III randomized, controlled clinical trial with two groups will be compared. 60 patients newly admitted to internal and trauma ICU of two medical, Educational and therapeutic centers of Sanandaj city related to Kurdistan University of Medical Sciences (KUMS) will be selected by convenience sampling and then will be allocated in two groups of 30 patients using random blocks module. **Inclusion criteria:** New patients admitted to the ICU with an endotracheal tube intubation and mechanical ventilation undergo less than 12 hours previously, and have at least 4 days of mechanical ventilation. **Exclusion criteria:** Patients with systemic infections, lung cancer, thrombocytopenia or other coagulopathies, diagnosed immunosuppressive disease, known allergy to chlorhexidine, honey and other complications of mouthwash solutions used in this study, leukopenia, having obvious symptoms of aspiration, pregnancy, organ transplants, oral mucositis, high blood sugar, oromaxillofacial surgery and extensive burns. **Interventions:** In both groups, mouthwash will be applied twice a day (8 am- 8 pm) until four days by two trained nurses using sterile technique. Honey mouthwash used in this study is native honey from Zagros Mountains of Kurdistan in west of Iran and is prepared by thyme and astragalus herbs. After confirming the honey in the laboratory of Kurdistan Agriculture Institution, honey mouthwash 12.5% will be prepared on a daily basis using sterile technique. Also, the solution of chlorhexidine 0.2% with commercial name Hexodyne used in this study is produced by World Health Co. with license no.44.13186 and approved by the ministry of health and the medical education of Iran. **Main outcome measures:** Swab

samples will be taken from the mouth and throat of all patients three times (before the intervention, 48 h and 96 h after the intervention), and will be transferred onto the Sheep' Blood Agar and Eosin Methylene Blue (EMB) Agar culture plates ,and after 24-48 hours plates will be investigated for bacterial growth and colonization. In cases of colonization, the biochemistry and morphologic tests will be used to determine pathogenic microorganisms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012412257N4**

Registration date: **2016-07-13, 1395/04/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-13, 1395/04/23

Registrant information

Name

Farhad Ramezani-Badr

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 24 3527 9412

Email address

ramazanibadr@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Zanjan University of

Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2015-09-05, 1394/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative effectiveness of honey 12.5% and chlorhexidine 0.2% mouthwash on the oropharyngeal bacterial colonization in mechanically ventilated Patients in ICU: A randomized control trial

Public title

Comparison of honey and chlorhexidine mouthwashes on the Patients' oral care in ICU

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18-65 years, New patients will admit to the ICU with an endotracheal tube intubation and mechanical ventilation undergo less than 12 hours previously, and have at least 4 days of mechanical ventilation. Exclusion criteria: Re-intubation and Re-admission to the ICU; transfer from another ICU; patients with pneumonitis and other systemic infections; a confirmed diagnosis of lung cancer; a evident signs of airway aspiration; a diagnosed thrombocytopenia (platelet count less than 40 and/or a INR>2 or other coagulopathy); anticoagulant therapy;a confirmed diagnosis of immunosuppression; high FBS, a known hypersensitivity to CHX and honey and other complication related to mouthwash solution used to in this study; leukopenia, HIV; pregnant women; organ transplant patients; oral mucositis; advanced periodontal disease; long term steroid therapy; Oral and maxillofacial surgery; extensive burns; contraindication for semi fowlers' position; absence of inform consent.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

According to difference between color of mouthwash solutions, it is impossible blindness for researchers and participants.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi Blv, Zanjan

City

Zanjan

Postal code

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

ZUMS.REC.1392.40

Health conditions studied

1

Description of health condition studied

oropharyngeal colonization

ICD-10 code

J15

ICD-10 code description

Bacterial pneumonia, not elsewhere classified

2

Description of health condition studied

oropharyngeal colonization

ICD-10 code

J15.0

ICD-10 code description

Pneumonia due to Klebsiella pneumoniae

3

Description of health condition studied

oropharyngeal colonization

ICD-10 code

J15.1

ICD-10 code description

Pneumonia due to Pseudomonas

4

Description of health condition studied

oropharyngeal colonization

ICD-10 code

J15.2

ICD-10 code description

Pneumonia due to staphylococcus

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

oropharyngeal colonization

Timepoint

before intervention, 48 and 96 hours after intervention

Method of measurement

blood agar and EMB medium

Secondary outcomes

empty

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

Oral rinse with 12.5% honey solution will be done twice a day (8AM-8PM) with a sterile technique and during complete 4 days by two trained nurses.

Category

Prevention

2**Description**

Oral rinse with 0.2% chlorhexidine solution will be done twice a day (8AM-8PM) with a sterile technique and during complete 4 days by two trained nurses.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

ICU trauma, Medical, Educational and therapeutic center of Besat-Kurdistan University of Medical Sciences

Full name of responsible person

Halimeh Amiri

Street address

Medical, Educational and therapeutic center of Besat, Keshavarz ave, Sanandaj, Kurdistan

City

Sanandaj

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

ICU, Medical, Educational and therapeutic center of Tohid-Kurdistan University of Medical Sciences

Full name of responsible person

Halimeh Amiri

Street address

Medical, Educational and therapeutic center of Tohid, Geryashan ave, Sanandaj, Kurdistan

City

Sanandaj

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

Vice-chancellery for Research, Zanzan University of Medical Sciences

Full name of responsible person

Dr Masoud Vakili

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Research management, Vice-chancellery for Research, Zanzan University of Medical Sciences, Zanzan, Iran

City

Zanzan

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

Yes

Title of funding source

Vice-chancellery for Research, Zanzan 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**

Zanzan University of Medical Sciences

Full name of responsible person

Farhad Ramezani-Badr

Position

Assistant Professor, Ph.D in Nursing

Other areas of specialty/work**Street address**

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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