Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Siences

Country

Iran (Islamic Republic of)

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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
befor 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 Sci
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice- chancellery for Research, Zanjan University of Medical Sciences
Full name of responsible person
Dr Masoud Vakili
Street address
Research management, Vice- chancellery for Research, Zanjan University of Medical Sciences, Zanjan, Iran
City
Zanjan
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, Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Farhad Ramezani-Badr
Position
Assistant Professor, Ph.D in Nursing
Other areas of specialty/work
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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