

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Comparing the effect of Ortodentol and chlorhexidine mouthwashes 10% and /12 percent on oral hygiene intubated patients in intensive care units

Protocol summary

Summary

The overall goal: Comparing of intubated patients in intensive care unit mouth rinse ortodentol and cholerhexzidin on oral health Interventions and Methods: convenience sampling and were randomly selected and single blind. The intervention group rinse the mouth with vegetable (ortodentol) and the control group with chlorhexidine mouth rinse with 15 mL each time with a soft toothbrush can be rinsed, and the suction within 30 seconds. Before rinsing the mouth at the interval (8, 48, 72 hours) from different areas of the mouth sample and agar cultured and assessment of oral hygiene by standard scale-back and plaque oral mucous measured and the questionnaire will be recorded Primary outcomes: Oral health, Studied groups, endotracheal tube intubation time, the oral microbial

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Recruitment status

Recruitment complete

Funding source

University of Medical Sciences (government)

Expected recruitment start date

2016-07-10, 1395/04/20

Expected recruitment end date

2016-10-11, 1395/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012232101N1**

Registration date: **2017-04-02, 1396/01/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-02, 1396/01/13

Registrant information

Name

Haydeh Heidari

Name of organization / entity

Medical University

Country

Iran (Islamic Republic of)

Phone

Scientific title

Comparing the effect of Ortodentol and chlorhexidine mouthwashes 10% and /12 percent on oral hygiene intubated patients in intensive care units

Public title

Comparing the effect of Ortodentol and chlorhexidine mouthwashes 10% and /12 percent on oral hygiene intubated patients in intensive care units

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria included: the patient has an endotracheal tube through the mouth ;with the age of 15-85 years ; 8 hours of intubation in the intensive care unit, before ; no history of allergy is to plant compounds Savory (carvacrol) ; Lack of any damage characterized by endotracheal intubation or planes in the mouth Lesion is unknown. Exclusion criteria included: transmission or discharge or death of the patient from the intensive care unit before the study was completed ; Creating profit any damage characterized by endotracheal intubation or

planes or other physical Hram ; Lack of desire to continue to study the patient's legal guardian ; and immune system dysfunction, radiotherapy and chemotherapy and having any malignant disease.

Age

From **15 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord, Medical,University Ethics Committee

Street address

Blvd , Kashani,

City

Shahrekord

Postal code

8815713471

Approval date

2016-07-10, 1395/04/20

Ethics committee reference number

IR.SKUMS.REC.1395.122

Health conditions studied

1

Description of health condition studied

Chronic Obstruactive Pulmanary Disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

2

Description of health condition studied

Diabeteic Mellitus

ICD-10 code

E10,E14

ICD-10 code description

Diabetes mellitus

3

Description of health condition studied

Respiratory Distress Syndrome

ICD-10 code

J80

ICD-10 code description

Adult respiratory distress syndrome

4

Description of health condition studied

Multiple Truma

ICD-10 code

T00,T07

ICD-10 code description

Injuries involving multiple body regions

5

Description of health condition studied

Cerebral Vascular Attacke

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

6

Description of health condition studied

Gastrointestinal haemorrhage

ICD-10 code

K92.2

ICD-10 code description

Gastrointestinal haemorrhage, unspecified

7

Description of health condition studied

Poisoning

ICD-10 code

T96

ICD-10 code description

Sequelae of poisoning by drugs, medicaments and biological substances

8

Description of health condition studied

laparatomy

ICD-10 code

Y60

ICD-10 code description

Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care

9

Description of health condition studied

Intracerebral haemorrhage

ICD-10 code

I69

ICD-10 code description

Sequelae of cerebrovascular disease

Primary outcomes

1

Description

Oral Health

Timepoint

Before and after the intervention

Method of measurement

Beck standard questionnaire and measured plaque and oral mucosal

Secondary outcomes

1

Description

Malnutrition

Timepoint

Scale

Method of measurement

Relative

2

Description

Side Effect

Timepoint

Scale

Method of measurement

Relative

Intervention groups

1

Description

The intervention group (mouthwash ortodontoll) ortodentol mouthwash solution containing 10% carvacrol extracts pharmaceutical company Khorramabad, Lorestan building twice a day (morning and evening) each time mouthwash is 15 mm Lytrba used syringes and Ghshh to brush and suction the patient's mouth in 30 seconds.

Category

Prevention

2

Description

The control group (chlorhexidine)Control (chlorhexidine) solution of chlorhexidine / 12% Manufacturing Co. World Health Tehran twice a day (morning and evening)

patients intubated mouth rinse with a solution of 15 ml is washed with brushes and suction is then washed and the amount and Read mouth rinse is similar to the intervention group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani , Hospital ,Shahrekord

Full name of responsible person

Hayede Heidari

Street address

School ,of Nursing og Ljós móðurfræði, Shahrekord

City

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2

Recruitment center

Name of recruitment center

Vali-e-ASR , Hospital , Borūjen

Full name of responsible person

Hojat Mirzakhani

Street address

Blvd , Nation

City

Borūjen

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice , President , Research and Technology , University of Medical Sciences

Full name of responsible person

Dr Abdul Rahim Kazemi

Street address

Blvd , Kashani

City

Shahrekord

Grant name

معاونت پژوهشی و فناوری دانشگاه علوم پزشکی شهرکرد

Grant code / Reference number

2243

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

Yes

Title of funding source

Vice , President , Research and Technology , 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

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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