Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of effect of three mouthwashs, chlorhexidin, sodium bicarbonate and salin on bacterial colonization of endotracheal tubes and incidence of pneumonia in patients undergoing open heart surgery in Imam Ali Hospitat 2012-2013.

Protocol summary

Summary

Objective: to compare the incidence of pneumonia and bacterial colonization of endotracheal tubes in patients using three mouthwash solutions: sodium bicarbonate, chlorhexidin and normal saline. study design: double-blind. Study population: Patients undergoing open heart surgery and admitted to the intensive care unit at Imam Ali hospital. Major inclusion criteria:having an endotracheal tube, being under mechanical ventilation, absence of pneumonia and periodontal disease. Major exclusion criteria: removal of endotracheal tube within 6 hour after surgery. Sample Size: 165 patients. Intervention: using three mouthwash solutions: sodium bicarbonate, chlorhexidin 0.2% and normal saline. Time of intervention:All of the patients should wash their mouths with the mouthwash from 24 hours before surgery and twice a day (8 am and 8 pm). Immediately after surgery, until extubation, mouthwash will be conducted by the researcher in ICU for 48-72 hours. After discharging from ICU, up to 7 days, mouthwash is performed by patients. Primary outcomes: Being diagnosed with nosocomial pneumonia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207204736N3**
Registration date: **2012-07-26, 1391/05/05**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-07-26, 1391/05/05

Registrant information

Name
Alireza Khatony

Name of organization / entity
Kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Kermanshah University of Medical Sciences

Expected recruitment start date
2012-08-05, 1391/05/15

Expected recruitment end date
2012-11-21, 1391/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of effect of three mouthwashs, chlorhexidin, sodium bicarbonate and salin on bacterial colonization of endotracheal tubes and incidence of pneumonia in patients undergoing open heart surgery in Imam Ali Hospitat 2012-2013.

Public title

Effect of mouthwash on tracheal colonization and pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria consist of: lack of history of recent intubation; no history of recent surgery; no sensitivity to mouthwash solutions; having endotracheal tube; no symptoms of aspiration; the absence of debilitating disease of immune system; lack of use immunosuppressive drugs; age between 18-65 years and lack of periodontal disease. Exclusion criteria consist of: the patient died during surgery or the day after surgery; tracheal tube out before 6 hours after surgery; view aspiration revealed and incidence of allergic and unwanted reactions to chlorhexidin.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **165**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

kermanshah University of Medical Sciences

Street address

Shahid Beheshty BLV

City

Kermanshah

Postal code

Approval date

2012-06-26, 1391/04/06

Ethics committee reference number

4147/420/7/پ

Health conditions studied

1

Description of health condition studied

pneumonia

ICD-10 code

J18.8

ICD-10 code description

Other pneumonia, organism unspecified

Primary outcomes

1

Description

The amount of bacterial colonization of endotracheal tube

Timepoint

When extubation of tracheal tube

Method of measurement

Doing culture from endotracheal tube cuff in a laboratory

2

Description

Incidence of pneumonia

Timepoint

From entering to ICU and up to 7 days after admitted to surgical ward

Method of measurement

Chest radiography, measurement of body temperature, A complete blood count

Secondary outcomes

empty

Intervention groups

1

Description

For the first group, two times a day and for 7 days after surgery, chlorhexidin 0.2% solution is used.

Category

Prevention

2

Description

For the second group, two times a day and for 7 days after surgery, solution of sodium bicarbonate is used.

Category

Prevention

3

Description

For the third group, two times a day and for 7 days after surgery, normal saline solution, is used.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Ali Hospital

Full name of responsible person
Dr Gholamreza Morady

Street address
Shahid Beheshty Blvd,

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr Farid Najafy

Street address
Shahid Beheshty Boulevard, Kermanshah University of Medical Sciences

City
Kermanshah

Grant name

Grant code / Reference number

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

Title of funding source
Kermanshah 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
Kermanshah School of Nursing and Midwifery

Full name of responsible person
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Position
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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