

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison the effect of Zataria Multiflora Boiss%0.5 oral solution and chlorhexidine on bacterial pathogens of Ventilator Associated Pneumonia (VAP) in patient admitted in cardiac surgery intensive care unit

Protocol summary

Summary

The purpose of this study is evaluation the antimicrobial effect of Zataria Multiflora Boiss on colony numbers of bacterial pathogens of Ventilator Associated Pneumonia in patients undergoing cardiac surgery and are admitted in cardiac surgery intensive care unit. This is a randomized, double-blind, placebo- controlled, single-center trial. Sixty patients being undergo open cardiac surgery and are admitted in cardiac surgery intensive care unit at Rohani hospital, babol, will enter the trial. inclusion criteria: patients with age between 50-70 years, who underwent open heart surgery; dentate patients; admitted in intensive care unit minimum 2 days and maximum 5 days; intubation minimum 12 hours. exclusion criteria: Patients with emergent surgery; preoperative antibiotic therapy; preoperative respiratory infection; history of radiotherapy; history of corticosteroid therapy; hypersensitivity to chlorhexidine; oral mucosal lesions; advanced periodontitis; active caries; pregnancy death. Patients are randomly allocated in 3 groups of 20. The first group will receive Zataria Multiflora Boiss%0.5 oral solution , second group receive chlorhexidine 0.12% oral solution,the third group receive placebo three times a day, since the beginning of intubation, up to the end of extubation. we will need two sampling from oropharynx mucosa; the first one will be performed at the very beginning of intubation and second one will be performed at the end of extubation. the primary and secondary numbers of colony of bacteria, Pseudomonas aeruginosa, Acinetobacter and entrobacter, will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011225986N1**

Registration date: **2016-03-04, 1394/12/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-04, 1394/12/14

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2016-02-09, 1394/11/20

Expected recruitment end date

2016-10-11, 1395/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Zataria Multiflora Boiss%0.5 oral solution and chlorhexidine on bacterial pathogens of

Ventilator Associated Pneumonia (VAP) in patient admitted in cardiac surgery intensive care unit

Public title

Effect of Zataria Multiflora Boiss On Ventilator Associated Pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: patients with age between 50-70 years, who underwent open heart surgery; dentate patients; admission in intensive care unit minimum 2 days and maximum 5 days; intubation minimum 12 hours.
exclusion criteria: Patients with emergent surgery; preoperative antibiotic therapy; preoperative respiratory infection; history of radiotherapy; history of corticosteroid therapy; hypersensitivity to chlorhexidine; oral mucosal lesions; advanced periodontitis; active caries; pregnancy death

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Babol University of Medical Science

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Babol University of Medical Science, Ganj Afrooz Avenue, Babol, Mazandaran, Iran

City

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Postal code**Approval date**

2015-12-06, 1394/09/15

Ethics committee reference number

MUBABOL.REC.1394.221

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

Pneumonia

ICD-10 code

J15

ICD-10 code description

Bacterial pneumonia, not elsewhere classified

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

Infection with Acinetobacter bacteria

Timepoint

at the beginning of intubation, at the end of extubation

Method of measurement

Colony Count

2**Description**

Infection With Enterobacter bacteria

Timepoint

at the beginning of intubation, at the end of extubation

Method of measurement

Colony Count

3**Description**

Infection With Pseudomonas aeruginosa

Timepoint

at the beginning of intubation, at the end of extubation

Method of measurement

Colony Count

Secondary outcomes

empty

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

Zataria Multiflora Boiss%0.5 oral solution three times a day up to the end of extubation

Category

Prevention

2**Description**

Chlorhexidine 0.12% oral solution three times a day up to the end of extubation

Category

Prevention

3

Description

Placebo(normal saline) oral solution three times a day up to the end of extubation

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rohani Hospital

Full name of responsible person

Atena Shirzad

Street address

Rohani Hospital, Ganj afrooz Avenue, Babol, Mazandaran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences, Deputy of Research & Technology

Full name of responsible person

Ali Akbar Moghadamnia

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Babol University of Medical Sciences, Deputy of Research & Technology, Ganj afrooz Avenue, Babol, Mazandaran, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol University of Medical Sciences, Deputy of Research & Technology

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

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Name of organization / entity

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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