Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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; tha 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

Name

Atena Ahirzad

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3229 1408

Email address

a.shirzad@mubabol.ac.ir

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; admition inintensive 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
Street address
Babol University of Medical Science, Ganj Afrooz Avenue, Babol, Mazandaran, Iran
City
Babol
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
Infetion with Acinetobacter bacteria
Timepoint
at the begining of intubation, at the end of extubation
Method of measurement
Colony Count

2

Description
Infection With Enterobacter bacteria
Timepoint
at the begining of intubation, at the end of extubation
Method of measurement
Colony Count

3

Description
Infection With Pseudomonas aeruginosa
Timepoint
at the begining 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
City
Babol

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

Contact
Name of organization / entity
Babol University of Medical Science
Full name of responsible person
Ghasem Faghanzadeh Ganji
Position
Assistant Professor
Other areas of specialty/work
Street address
Babol University of Medical Science, Ganj Afrooz Avenue, Babol, Mazandaran, Iran
City
Babol
Postal code
Phone
+98 11322383015
Fax
Email
ghf.ganji@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Science
Full name of responsible person
Atena Shirzad
Position
Asistant professor
Other areas of specialty/work
Street address
Dental School, Babol University of Medical Science, Ganj Afrooz Avenue, Babol, Mazandaran, Iran
City
Babol
Postal code
Phone
+98 11 3229 1408
Fax
Email
ats60dent@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Science
Full name of responsible person
Atena Shirzad
Position
Assistant Professor
Other areas of specialty/work
Street address
Dental School, Babol University of Medical Science, Ganj Afrooz Avenue, Babol, Mazandaran, Iran
City
Babol
Postal code
Phone
+98 11 3229 1408

Fax

Email

ats60dent@yahoo.com

Web page address

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