

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparsion the effects of Echinacea and normalsaline mouthwashes on Ventilator Associated Pneumonia in intubated patients in intensive care units. Arak

Protocol summary

Summary

Objectives: The objective of this study is to compare the effect of Echinacea and normal saline mouthwash solutions on ventilator associated pneumonia. **Design:** This is a randomized clinical trial. **Setting and conduct:** Method, time and frequency of mouthwash in both groups will be performed the same way. For diagnosing ventilator associated pneumonia, clinical pulmonary infection score (CPIS) will be completed before and in the fifth day of intervention and the incidence rate of pneumonia will be compared in the two groups. **Participants:** Participants are 70 intubated patients admitted to intensive care units of Valiasr hospital in Arak city which were randomly allocated into two intervention and control group groups. **Inclusion criteria** included having a tracheal tube; aged 18-65 years; less than 12 hours of hospitalization in the intensive care unit; and **exclusion criteria** included patients transferred from the intensive care unit; patients died before completion of the study; any damage caused by endotracheal intubation or any other physical causes; antibiotic use before admission; admission in other units before intensive care unit; pregnancy; history of allergy to herbal substances; and chronic diseases of immune system. **Intervention:** Mouthwash in both groups will be performed the same way, two times a day, for 5 days. Mouthwash in intervention and control groups will be performed with Echinacea and normal saline mouthwash solutions, respectively. **Main outcome measures (variables):** The main measure is ventilator associated pneumonia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080518694N1**

Registration date: **2014-10-28, 1393/08/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-28, 1393/08/06

Registrant information

Name

Maryam Gholami Mehrabadi

Name of organization / entity

Arak University of Medical Sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Arak University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparsion the effects of Echinacea and normalsaline mouthwashes on Ventilator Associated Pneumonia in

intubated patients in intensive care units. Arak

Public title

Effects of Echinacea on Ventilator – Associated Pneumonia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: having a tracheal tube; aged 18-65 years; less than 12 hours of hospitalization in the intensive care unit before. Exclusion criteria: patients transferred from the intensive care unit; patients died before completion of the study; any damage caused by endotracheal intubation; airway or any other physical cause; antibiotic use before admission; admission in other units before intensive care unit; pregnancy; history of allergy to herbal substances; chronic diseases of immune system.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Arak University of Medical Sciences

Street address

Arak University of Medical Sciences; Sardasht; street; Arak; Iran

City

Arak

Postal code

3848176941

Approval date

2014-05-21, 1393/02/31

Ethics committee reference number

1100

Health conditions studied

1

Description of health condition studied

Ventilator Associated Pneumonia

ICD-10 code

J17.0

ICD-10 code description

Pneumonia in diseases classified elsewhere

Primary outcomes

1

Description

Ventilator Associated Pneumonia

Timepoint

Before intervention and in the fifth day of intervention

Method of measurement

Clinical Pulmonary Infection Score (CPIS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Echinacea mouthwash 1%, 30cc, two times a day using a toothbrush for fifth days

Category

Treatment - Drugs

2

Description

Control group: normal saline mouthwash using a toothbrush, 30cc, two times a day using a toothbrush for fifth days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital Arak

Full name of responsible person

Maryam Gholami Mehrabadi

Street address

Valiasr hospital; Valiasr street; Arak; Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Mr. Babai

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Arak University of Medical Sciences; Sardasht street; Arak; 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

Vice chancellor for research, Arak 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**

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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