

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Efficacy of absorbable dressing foam on prevention of tracheostomy site infections

Protocol summary

Summary

This study is semi experimental clinical trial. In this trial, eighty ICU patients that they have 18-60 Y/O and low GCSS (Glasgow Coma Scale Score) because of head injury are enrolled. The level of consciousness of these patients, according to clinical information, diagnostic CT scan and Counseling with Neurologist, will not rise up to 21 days. Therefore, they are undergoing tracheostomy surgery at the first 3 days after ICU admission. Then the eligible patients randomly allocated into one of two groups. In the intervention group, the absorbable foams are used for dressing of theracheostomy site for 7 days and in the control group the normal gas are used for dressing of theracheostomy site for 7 days. These absorbable dressing foams or normal gas are put on in the theracheostomy site immediately after theracheostomy surgery. Then the culture samples from the tracheostomy site are prepared in 24, 72, 168 hours after tracheostomy surgery and sent to the laboratory as blind. These Patients should receive the same antibiotics in ICU. The patients with Diabetes, Pneumonia, Renal failure, Hepatic failure, Chronic cardiopulmonary disorders, history of antibiotic therapy from last, clear infection signs in anterior neck, anterior neck burning and foam sensitivity are excluded from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205215426N5**

Registration date: **2012-07-17, 1391/04/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-17, 1391/04/27

Registrant information

Name

Mehdi Ahmadinejad

Name of organization / entity

Anesthesiology department, Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 0223 5011

Email address

m.ahmadinejad@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences Research Center

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of absorbable dressing foam on prevention of tracheostomy site infections

Public title

Efficacy of absorbable dressing foam on prevention of tracheostomy site infections

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Eighteen to sixty Y/O patients; the patients with low GCSS (Glasgow Coma Scale Score) because of head injury that this score, will not increase

in up to 21 days, according to clinical information, diagnostic CT scan and Counseling with Neurologist; the Patients that undergoing tracheostomy at the first 3 days after ICU admission and all the Patients should receive the same antibiotics in ICU. Exclusion Criteria: the patients with Diabetes; Pneumonia; Renal failure; Hepatic failure; Chronic cardiopulmonary disorders; history of antibiotic therapy from last; clear infection signs in anterior neck; anterior neck burning and foam sensitivity.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Kerman University of Medical Sciences Research Center Ethics Committee

Street address

Jahad street, Kerman University of Medical Sciences Research Center

City

kerman

Postal code**Approval date**

2012-06-17, 1391/03/28

Ethics committee reference number

ka/91/63

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

Tracheostomy site infections

ICD-10 code

J95.0

ICD-10 code description

Tracheostomy malfunction

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

Tracheostomy site infections

Timepoint

The culture samples from the tracheostomy site are prepared in 24, 72, 168 hours after tarcheostomy surgery

Method of measurement

The prepared culture samples from the tracheostomy site, sent to the laboratory as blind and followed up for result.

Secondary outcomes

empty

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

Intervention group: The absorbable foams are used for dressing of theracheostomy site for 7 days.

Category

Prevention

2**Description**

Control Group: The normal gas are used for dressing of theracheostomy site for 7 days.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

ICU ward, Shahid Bahonar hospital

Full name of responsible person

Mehdi Ahmadinejad

Street address

Shahid Bahonar hospital of Kerman

City

Kerman

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Kerman University of Medical Sciences Research Center

Full name of responsible person

Dr. Malekpour Afshar

Street address

Kerman University of Medical Sciences Research Center

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences Research Center

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

Kerman University of Medical Sciences

Full name of responsible person

Dr. Mehdi Ahmadi nejad

Position

Assistant professor - Fellowship in critical care

Other areas of specialty/work

Street address

ICU ward, Shahid Bahonar hospital

City

Kerman

Postal code

Phone

+98 34 1223 5011

Fax

Email

mehdia50@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Mehdi Ahmadi nejad

Position

Assistant professor - Fellowship in Critical care

Other areas of specialty/work

Street address

ICU ward, Shahid Bahonar hospital

City

Kerman

Postal code

Phone

+98 34 1223 5011

Fax

Email

mehdia50@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Mehdi Ahmadi nejad

Position

Assistant professor - Fellowship in Critical care

Other areas of specialty/work

Street address

Kerman University of Medical Sciences

City

Kerman

Postal code

Phone

+98 34 1223 5011

Fax

Email

mehdia50@gmail.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