

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of Ondansetron compared with placebo on prevention of Ventilator associated pneumonia in ICU

Protocol summary

Summary

The aim of this study is to evaluate the effect of Ondansetron on prevention of Ventilator associated pneumonia in ICU. This study design is as a kind of intervention no-blinded randomized clinical trial that perform on 80 patients intubated with an endotracheal tube hospitalized in intensive care units in Shahrekord kashani hospital. Patients will be randomly divided into two groups of 40 people of case and control. Inclusion criteria: patients aged 15-65 years; with the full consent of the patient protector; the patient respiratory support with ventilation; more than 48 hours hospitalization in the ICU. Exclusion criteria: patients out of the age range 15-65 years; patients with suspected pulmonary health is arrival; the lack of satisfaction of the patient protector. Intervention: to case group is injected 4 milligram Ondansetron and to case group is injected 4 milligram placebo, each one twice daily for five days, then primary outcome include the rate of Ventilator associated pneumonia and secondary outcomes include fever, leukopenia, purulent sputum, cough and shortness of breath will be analyzed daily for 5 days in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406156480N6**

Registration date: **2015-10-06, 1394/07/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-06, 1394/07/14

Registrant information

Name

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Name of organization / entity

Shahrekord University of Medical Sciences

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+98 38 1334 9509

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mtmoradi@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahrekord University of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ondansetron compared with placebo on prevention of Ventilator associated pneumonia in ICU

Public title

The effect of Ondansetron on prevention of Ventilator associated pneumonia in ICU

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 15-65 years; with the full consent of the patient protector; the patient respiratory support with ventilation; more than 48 hours hospitalization in the ICU Exclusion criteria: patients out of the age range 15-65 years; patients with suspected

pulmonary health is arrival; the lack of satisfaction of the patient protector.

Age

From **15 years** old to **65 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)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study sampling method is a table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Rahmatie, Shahrekord

City

shahrekord

Postal code

8815713471

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

901033

Health conditions studied

1

Description of health condition studied

Pneumonia

ICD-10 code

J17

ICD-10 code description

Pneumonia in diseases classified elsewhere

Primary outcomes

1

Description

Ventilator associated pneumonia

Timepoint

Before and 5 days after the intervention, once a day

Method of measurement

Chek list (based on clinical symptoms and laboratory)

Secondary outcomes

1

Description

Fever over 38 ° C without any known other infectious focus

Timepoint

Before and 5 days after the intervention, once a day

Method of measurement

Clinical signs

2

Description

Leukopenia

Timepoint

Before and 5 days after the intervention, once a day

Method of measurement

Lab data

3

Description

Purulent sputum

Timepoint

Before and 5 days after the intervention, once a day

Method of measurement

Clinical signs

4

Description

Create new cough or worsening cough previous or shortness of breath or increased respiratory rate

Timepoint

Before and 5 days after the intervention, once a day

Method of measurement

Clinical signs

5

Description

Disruption of blood gases

Timepoint

Before and 5 days after the intervention, once a day

Method of measurement

Lab data

Intervention groups

1

Description

Intervention group: injection 4 milligram Ondansetron twice a day for 5

Category

Prevention

2

Description

Control group: injection 4 milligram placebo twice a day for 5 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord kashani hospital

Full name of responsible person

Dr Hossein Madineh

Street address

Kashani hospital, Parastar Street, Shahrekord

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, shahrekord University of Medical Sciences

Full name of responsible person

Dr Mahmoud Mobasheri

Street address

Vice Chancellor for research, Shahrekord University of Medical Sciences, Kashani Street, Shahrekord

City

shahrekord

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, shahrekord 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

Shahrekord University of Medical Sciences

Full name of responsible person

Dr Hossein Madineh

Position

Anesthesiologist

Other areas of specialty/work

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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