

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The comparison of efficacy and safety of vancomycin and teicoplanin in hospitalized children with severe pneumonia

Protocol summary

Summary

This study is a clinical trial on 100 children aged 2 months to 12 years admitted in Pediatrics Intensive Care Unit of Kashan Beheshti Hospital with complaints of fever, tachypnea and respiratory distress in 2015. Severe pneumonia is confirmed by chest radiography. Patients with the history of pulmonary disease including asthma, documented heart disease or other chronic disease, renal disease, immunodeficiency and malnutrition or growth failure are excluded from the study. Patients randomly assign into two groups. The first group receives vancomycin prepared by Jaber Pharma Company 10 milligram per kilogram of body weight every 6 hours and the second group will receive teicoplanin prepared by Aventis Pharma Company 10 milligram per kilogram of body weight daily. Other treatment protocols for pneumonia shall be conducted in two groups. Creatinine measurements will be performed daily. Duration of fever, tachypnea and respiratory distress, adverse events (nephrotoxicity and red man syndrome) and Length of hospital stay will be recorded by the question of nurses and study of dossier.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030111145N13**

Registration date: **2015-03-16, 1393/12/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-16, 1393/12/25

Registrant information

Name

Mohammad Reza Sharif

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

sharif_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2015-03-16, 1393/12/25

Expected recruitment end date

2016-03-15, 1394/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of efficacy and safety of vancomycin and teicoplanin in hospitalized children with severe pneumonia

Public title

The comparison of vancomycin and teicoplanin in treatment of hospitalized children with severe pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children 2 months to 12 years old hospitalized in Pediatrics Intensive Care Unit of Kashan Beheshti Hospital; fever (axillary temperature 37.5° C or more); tachypnea; respiratory distress. Exclusion criteria:

the history of pulmonary disease including asthma; documented heart disease or other chronic disease; renal disease; immunodeficiency; malnutrition or growth failure.

Age

From **2 months** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran

City

Kashan

Postal code

Approval date

2015-03-05, 1393/12/14

Ethics committee reference number

5750

Health conditions studied

1

Description of health condition studied

Pneumonia

ICD-10 code

J18.9

ICD-10 code description

Pneumonia, unspecified

Primary outcomes

1

Description

Fever improvement

Timepoint

Every 6 hours

Method of measurement

Mercury thermometer with axillary method

2

Description

Tachypnea improvement

Timepoint

Daily

Method of measurement

Breathing rate

3

Description

Improvement of respiratory distress

Timepoint

Daily

Method of measurement

Observed breathing

Secondary outcomes

1

Description

Renal failure

Timepoint

Daily

Method of measurement

creatinin measurement (milligram/deciliter)

2

Description

Red man syndrome

Timepoint

During injection.

Method of measurement

Observed by nurse

3

Description

Duration of hospital stay

Timepoint

At discharge

Method of measurement

Days recorded in dossier

Intervention groups

1

Description

Intervention group 1: Intravenous infusion of vancomycin
10 mg/kg every 6 hours

Category

Treatment - Drugs

2

Description

Intervention group 2: Intravenous infusion of teicoplanin
10 mg/kg daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr. Mohammad Reza Sharif

Street address

Shahid Beheshti Hospital, Ghotbe Ravandi Blvd,
Kashan, Iran

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

Street address

Kashan University of Medical Sciences, Ghotbe
Ravandi Blvd, Kashan, Iran

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Sharif

Position

Associate Professor, Pediatric Infectious Diseases
Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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