

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparative Efficacy of Levofloxacin versus Ceftriaxone and Azithromycin for Treating Community Acquired Pneumonia

Protocol summary

Study aim

To compare the treatment outcomes of levofloxacin alone with combination therapy of azithromycin and ceftriaxone for treating CAP in hospitalized patients having a CURB-65 score of ≤ 02 with mild to moderate CAP.

Design

Single-center, two-arm, parallel-group, open-label randomized controlled trial. A total of 150 participants will be randomly allocated in a 1:1 ratio to receive either levofloxacin or ceftriaxone plus azithromycin.

Settings and conduct

The trial will be conducted at the Pulmonology Department, Sheikh Zayed Medical College, Rahim Yar Khan, Pakistan. Eligible hospitalized adults will be screened and enrolled after written informed consent. Participants will be randomly allocated 1:1 to levofloxacin or ceftriaxone plus azithromycin and monitored during hospitalization for treatment response, adverse events and study outcomes. The trial is open-label.

Participants/Inclusion and exclusion criteria

Adults aged 18–70 years, of either sex, with mild-to-moderate community-acquired pneumonia and a Confusion, Urea, Respiratory rate, Blood pressure and age 65 years or older (CURB-65) score of 2 or less will be included. Patients with major drug allergy to study antibiotics, pregnancy or breastfeeding, HIV/AIDS, or more than 24 hours of prior antibiotic treatment for the current illness will be excluded.

Intervention groups

Levofloxacin group: levofloxacin 750 mg intravenously once daily for 5 days. Combination group: ceftriaxone 1 g intravenously twice daily plus azithromycin 500 mg intravenously once daily for 5 days.

Main outcome variables

Oxygen saturation (SpO₂), Length of hospital stay, Body temperature, Cough frequency and severity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260619069864N1**

Registration date: **2026-09-08, 1405/06/17**

Registration timing: **retrospective**

Last update: **2026-09-08, 1405/06/17**

Update count: **0**

Registration date

2026-09-08, 1405/06/17

Registrant information

Name

sundas kanwal

Name of organization / entity

Sheikh Zayed Hospital, Rahim Yar Khan

Country

Pakistan

Phone

+92 308 3606209

Email address

sundask95@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-01, 1404/09/10

Expected recruitment end date

2026-05-31, 1405/03/10

Actual recruitment start date

2025-12-01, 1404/09/10

Actual recruitment end date

2026-05-31, 1405/03/10

Trial completion date

2026-08-31, 1405/06/09

Scientific title

Comparative Efficacy of Levofloxacin versus Ceftriaxone and Azithromycin for Treating Community Acquired Pneumonia

Public title

Comparative Efficacy of Levofloxacin versus Ceftriaxone and Azithromycin for Treating Community Acquired Pneumonia

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-70 years. All patients with a diagnosis of mild to moderate CAP as per operational definitions that is CURB-65 score of 2 or less than 2 and having moderate severity according to APACHE II Score (APACHE score 11-20) Both male and female patients.

Exclusion criteria:

Radiography pictures of patients with cystic fibrosis show signs of empyema. Individuals with HIV/AIDS Individuals with a history of serious mental problems, seizures Individuals with a history of drug allergies to the study's medications. A lady who is nursing or pregnant. Already on antibiotic therapy before admission for the current illness (more than 24 hours).

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Actual sample size reached: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants who provide informed consent will be randomly allocated individually in a 1:1 ratio to either the levofloxacin group or the ceftriaxone plus azithromycin group. Simple randomization will be performed using a computer-generated random allocation sequence. The sequence will be generated before participant recruitment by an independent investigator who is not involved in recruitment or treatment. Sequentially numbered, opaque, sealed envelopes will be used for allocation concealment. After enrollment and baseline assessment, the next envelope in sequence will be opened to reveal the treatment assignment.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board- Sheikh Zayed Medical College/Hospital

Street address

Sheikh Zayed Medical College/ Hospital, Rahim Yar Khan

City

Rahim Yar Khan

Postal code

64200

Approval date

2025-02-28, 1403/12/10

Ethics committee reference number

117/IRB/SZMC/SZH

Health conditions studied

1

Description of health condition studied

Community Acquired Pneumonia

ICD-10 code

J18.9

ICD-10 code description

Pneumonia, unspecified organism

Primary outcomes

1

Description

oxygen saturation

Timepoint

3rd and 5th Day of Hospital Admission

Method of measurement

clinical assessment

2

Description

Length of hospital stay

Timepoint

At discharge

Method of measurement

Number of days from initiation of study treatment to hospital discharge, as recorded in the patient's hospital record.

Secondary outcomes

1

Description

Cough frequency and severity
Timepoint
Day 3 and Day 5 after initiation of treatment
Method of measurement
Patient-reported reduction in cough frequency and severity.

2

Description
Body temperature
Timepoint
Day 3 and Day 5 after initiation of treatment
Method of measurement
Measurement of body temperature using a standard clinical thermometer.

Intervention groups

1

Description
Intervention group: Levofloxacin 750 mg intravenously once daily for 5 days.
Category
Treatment - Drugs

2

Description
Control group: Ceftriaxone 1 g intravenously twice daily plus azithromycin 500 mg intravenously once daily for 5 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
pulmonology department, sheikh zayed hospital, Rahim Yar khan
Full name of responsible person
Dr Sundas Kanwal
Street address
pulmonology department, sheikh zayed hospital, Rahim Yar khan
City
Rahim Yar Khan
Postal code
64200
Phone
+92 308 3606209
Email
sundask95@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
sheikh zayed hospital
Full name of responsible person
dr sundas kanwal
Street address
rahim yar khan
City
rahim yar khan
Postal code
64200
Phone
+92 308 3606209
Email
sundask95@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
sheikh zayed hospital
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
SHEIKH ZAYED HOSPITAL, RAHIM YAR KHAN
Full name of responsible person
DR SUNDAS KANWAL
Position
POST GRADUATE REGISTRAR
Latest degree
Medical doctor
Other areas of specialty/work
PULMONOLOGY
Street address
RAHIM YAR KHAN
City
RAHIM YAR KHAN
Province
PUNJAB
Postal code
64200
Phone
+92 308 3606209
Email
sundask95@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

sheikh zayed hospital

Full name of responsible person

dr sundas kanwal

Position

PGR

Latest degree

Medical doctor

Other areas of specialty/work

pulmonology

Street address

hospital road

City

Rahim yar khan

Province

punjab

Postal code

64200

Phone

+92 308 3606209

Email

sundask95@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

sheikh zayed Hospital

Full name of responsible person

Dr sundas kanwal

Position

Registrar

Latest degree

Medical doctor

Other areas of specialty/work

pulmonology

Street address

hospital road

City

rahim yar khan

Province

punjab

Postal code

64200

Phone

+92 308 3606209

Email

sundask95@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Deidentified individual participant data will not be shared because participant consent does not include unrestricted data sharing. To protect participant confidentiality and comply with institutional ethics requirements, there is no current plan to make the IPD publicly available.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study Protocol and Informed Consent Form. These documents will be made available in PDF format after publication of the primary study results upon reasonable request to the corresponding investigator. All confidential information will be removed before sharing

When the data will become available and for how long

The documents will be available after publication of the primary study results and will remain available for five years thereafter upon reasonable request.

To whom data/document is available

Qualified researchers, clinicians, and academic investigators with a scientifically sound research proposal and appropriate institutional or ethics approval, if applicable.

Under which criteria data/document could be used

Documents will be shared upon reasonable request for legitimate scientific research purposes. Requests will be reviewed by the principal investigator. Recipients must agree to use the documents only for the approved research purpose and maintain confidentiality.

From where data/document is obtainable

Requests should be sent by email to the corresponding investigator. The study protocol and informed consent form will be provided electronically (PDF format) after approval of the request by the principal investigator.

What processes are involved for a request to access data/document

Researchers should submit a written request describing the research objectives and intended use of the documents. The principal investigator will review the request for scientific merit and ethical appropriateness. If approved, the requested documents will be shared electronically within 2-4 weeks.

Comments