Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 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 (SpO_2), 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 peroperational 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 Reveiw 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 Pnemonia

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
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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