Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

C reactive protein point of care testing for safely reducing the use of antibiotics for acute exacerbation of COPD

Protocol summary

Study aim

To compare the frequency of antibiotic use within four weeks of enrollment among patients with acute exacerbation of chronic obstructive pulmonary disease (AECOPD) managed using CRP point-of-care testing-guided antibiotic prescribing versus usual clinical care.

Design

Single-center, two-arm, open-label, parallel-group randomized controlled trial involving 164 patients (82 per group), with 1:1 computer-generated randomization and four-week follow-up. No blinding will be performed.

Settings and conduct

This open-label RCT will be conducted at Sheikh Zayed Hospital, Rahim Yar Khan. A total of 164 patients will be randomized into CRP-guided and usual-care groups, with follow-ups at weeks 1, 2, and 4. No blinding will be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 40–60 years. Both male and female patients. Patients with a previous clinical diagnosis of COPD presenting with acute exacerbation according to the study's operational definition. Exclusion criteria: Pregnant women. Antibiotic use within the preceding 5 days. Patients with malignancy. Patients unable or unwilling to provide informed consent or comply with the study protocol. Patients currently participating in or recently enrolled in another research study.

Intervention groups

Patients will be randomized into two groups. The intervention group will receive CRP-guided antibiotic management (CRP ≥20 mg/L), while the control group will receive usual clinical care. Both groups will be followed up at 1, 2, and 4 weeks to assess antibiotic use and clinical outcomes.

Main outcome variables

The primary outcome measure is the proportion of patients receiving antibiotics within four weeks of enrollment, compared between the CRP-guided group and the usual-care group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261102071643N1**
Registration date: **2026-11-07, 1405/08/16**
Registration timing: **retrospective**

Last update: **2026-11-07, 1405/08/16**
Update count: **0**

Registration date

2026-11-07, 1405/08/16

Registrant information

Name

Muhammad waqas Jamil

Name of organization / entity

Pulmonology department, Sheikh zayed Hospital

Country

Pakistan

Phone

+92 331 3304141

Email address

jamilwaqas4@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-01, 1404/11/12

Expected recruitment end date

2026-07-31, 1405/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
C reactive protein point of care testing for safely reducing the use of antibiotics for acute exacerbation of COPD

Public title
C reactive protein point of care testing for safely reducing the use of antibiotics for acute exacerbation of COPD

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 40-60 years Both genders Clinically diagnosed cases of AECOPD as per operational definition

Exclusion criteria:
Pregnant women. Patients who had received antibiotics within the past 5 days. Those involved in other research studies or those who had recently participated in the trial. Patients considered unable or unwilling to follow the protocol or provide consent. Malignancy

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **164**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients will be randomized individually in a 1:1 ratio into two parallel groups: the CRP point-of-care testing-guided group (Group A) and the usual-care group (Group B). Simple randomization will be performed using a computer-generated random sequence prepared through statistical software. Each participant will be assigned a unique study identification number, and the random allocation sequence will determine the treatment group. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE), prepared according to the computer-generated randomization sequence by an independent person not involved in patient recruitment or treatment allocation. After confirming eligibility and obtaining written informed consent, the investigator will open the next sequentially numbered envelope to determine the participant's group assignment. No stratification will be performed. The study will be open-label; therefore, blinding of patients and treating physicians will not be feasible. However, allocation concealment will be maintained until the participant has been enrolled and assigned to a group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ERB, Sheikh Zayed Hospital, Rahim Yar Khan

Street address
Hospital Road

City
Rahim Yar Khan

Postal code
64200

Approval date
2025-04-11, 1404/01/22

Ethics committee reference number
137/IRB/SZMC/SZH

Health conditions studied

1

Description of health condition studied
Acute exacerbation of chronic obstructive pulmonary disease (AECOPD).

ICD-10 code
J44.1

ICD-10 code description
Chronic obstructive pulmonary disease with (acute) exacerbation

Primary outcomes

1

Description
Proportion of patients receiving antibiotics in the CRP-guided group compared with the usual-care group.

Timepoint
Within four weeks of enrolment, assessed at initial consultation and follow-up visits at weeks 1, 2, and 4.

Method of measurement
Measured as the number and percentage of patients receiving at least one antibiotic prescription during the four-week follow-up period, based on clinical records and patient follow-up interviews, and compared between the two groups.

Secondary outcomes

1

Description
Proportion of patients receiving antibiotics at the initial consultation in both study groups.
Timepoint
At the initial consultation (baseline).
Method of measurement
Recorded as the number and percentage of patients prescribed antibiotics at the initial consultation, based on prescription records.

Intervention groups

1

Description
Intervention group: CRP-guided antibiotic prescribing. Patients will undergo CRP point-of-care testing, and antibiotic prescribing will be guided by CRP levels ≥20 mg/L in conjunction with clinical assessment by a consultant pulmonologist.
Category
Treatment - Other

2

Description
Control group: Usual care. Antibiotic prescribing will be based on clinical assessment and the judgment of the treating consultant pulmonologist without CRP point-of-care testing.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sheikh Zayed Hospital
Full name of responsible person
Dr Muhammad Waqas Jamil
Street address
Hospital Road
City
Rahim Yar Khan
Postal code
64200
Phone
+92 331 3304141
Email
jamilwaqas4@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sheikh Zayed Hospital
Full name of responsible person
Dr Muhammad Waqas Jamil
Street address
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City
Rahim Yar Khan
Postal code
64200
Phone
+92 331 3304141
Email
jamilwaqas4@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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Sheikh Zayed Hospital
Full name of responsible person
Dr Muhammad Waqas Jamil
Position
Speciality Registrar
Latest degree
Medical doctor
Other areas of specialty/work
pulmonology
Street address
Hospital Road
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Person responsible for scientific inquiries

Contact
Name of organization / entity

Sheikh Zayed Hospital

Full name of responsible person

Dr Muhammad Waqas Jamil

Position

Speciality Registrar

Latest degree

Medical doctor

Other areas of specialty/work

Pulmonology

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Person responsible for updating data

Contact

Name of organization / entity

Sheikh Zayed Hospital

Full name of responsible person

Dr Muhammad Waqas Jamil

Position

Speciality Registrar

Latest degree

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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

Due to patient confidentiality, data privacy concerns, and institutional ethical requirements, deidentified individual participant data will not be made publicly available.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Study Protocol: Final approved research protocol entitled "C-Reactive Protein Point-of-Care Testing for Safely Reducing the Use of Antibiotics for Acute Exacerbation of COPD." Statistical Analysis Plan: Document describing the planned statistical methods, outcome measures, and comparative analysis of the CRP-guided and usual-care groups.

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

The documents will be available to researchers, academic institutions, and healthcare professionals interested in conducting related clinical research.

Under which criteria data/document could be used

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

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 to the principal investigator stating the purpose of the request and intended use of the documents. Requests will be reviewed within 30 days, subject to institutional approval. Approved documents will be shared electronically

Comments

No individual participant data will be shared. Only the study protocol and statistical analysis plan will be made available under the specified conditions.