

Informed Consent Form

Evaluating Customized Antibiotic Duration (CAD) Strategy in Acute Exacerbations of COPD

Unique Protocol ID: IRB-113-07-08-25

DRAFT — Requires Institute Research Board and Ethics Committee (CDA Hospital) Review and Approval Before Use With Participants

1. Invitation to Participate

You are being invited to take part in a research study comparing two different lengths of antibiotic treatment for a flare-up (exacerbation) of your chronic lung condition, COPD (Chronic Obstructive Pulmonary Disease). Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask the study doctor or study team if anything is unclear, or if you would like more information. Take your time to decide whether you wish to take part.

2. Why Is This Study Being Done?

Doctors currently do not agree on how many days of antibiotics are needed to treat a COPD flare-up. Many hospitals in Pakistan, including this one, commonly use a 14-day course, but some international guidelines suggest that a shorter course (around 5-7 days) may work just as well, with fewer side effects. This study will compare a 7-day antibiotic course with the usual 14-day course to see if the shorter course works as well as the longer one, without increasing the risk of your symptoms coming back or getting worse.

3. Why Have I Been Asked to Take Part?

You have been asked to take part because you have been admitted to hospital with a flare-up of COPD that your doctor believes needs antibiotic treatment, and you meet the study's other entry requirements.

4. Do I Have to Take Part?

No. Taking part in this study is entirely your choice. If you decide to take part, you will be asked to sign this consent form. You are free to withdraw from the study at any time, without giving a reason, and without it affecting the standard medical care you receive now or in the future.

5. What Will Happen to Me If I Take Part?

If you agree to take part, you will be assigned by chance (like flipping a coin), to one of two groups:

- Group A: You will receive a 14-day course of antibiotic treatment (the usual treatment given at this hospital).
- Group B: You will receive a 7-day course of antibiotic treatment, followed by no further antibiotics for this flare-up unless your doctor decides you need them.

Neither you nor your study doctor will be able to choose which group you are in — this is decided randomly, and this is not a blinded study, meaning you and your doctor will know which treatment group you are in. The specific antibiotic medicine used will be chosen by your treating physician based on your individual condition, in the same way it would be if you were not part of this study — only the planned number of days of treatment differs between the two groups.

All other aspects of your care — including any tests, chest examinations, education about your condition, and general COPD management — will be the same regardless of which group you are in.

The study team will follow up with you at set time points (during your hospital stay, and after discharge, up to around Day 30) to check on your symptoms, whether you have needed any further antibiotics, and whether you have been readmitted to hospital.

Your total participation in follow-up assessments is expected to last up to approximately 30 days from the start of your treatment.

6. What Are the Possible Risks or Discomforts?

The antibiotics used in this study are standard medicines already used routinely to treat COPD flare-ups; you are not receiving an experimental drug, only a different planned duration of treatment.

- There is a possibility that a shorter (7-day) course of antibiotics may not fully treat your infection in some individuals, which could mean your symptoms take longer to improve, come back, or that you may need additional antibiotics or hospital care.
- All antibiotics can cause side effects such as an upset stomach, diarrhoea, nausea, rash, or, rarely, more serious allergic reactions — these risks are the same as if you were receiving antibiotic treatment outside of this study.
- There may be discomfort or inconvenience associated with additional study-related follow-up visits or phone calls after you leave the hospital.

The study team will monitor you closely throughout your treatment and follow-up. If at any time your doctor believes you need a longer course of antibiotics or any other treatment, you will receive it, and you may be withdrawn from the study treatment while remaining in follow-up if you agree.

7. Are There Any Benefits to Taking Part?

You may not personally benefit directly from taking part in this study. However, the information gained may help doctors understand whether shorter antibiotic courses are as effective as longer ones for treating COPD flare-ups, which could reduce unnecessary antibiotic use and side effects for future patients, and help address the growing global problem of antibiotic resistance.

8. What Happens If Something Goes Wrong?

If you experience a medical problem that you believe is related to your participation in this study, you should contact the study team immediately using the contact details below. You will receive appropriate medical care regardless of which study group you are in. [Sponsor/Institution to confirm and insert local policy on compensation for study-related injury, consistent with institutional and regulatory requirements.]

9. Will My Taking Part in the Study Be Kept Confidential?

Yes. All information collected about you during this study will be kept strictly confidential. Your medical records will be identified using a study code rather than your name wherever possible. Only the study team, and, where required, the sponsor, ethics committee, or regulatory authorities, will have access to your identifiable information, for the purposes of conducting and overseeing the study. Your data may be reported in scientific publications, but you will never be identified by name.

10. Will My Data Be Shared?

Individual participant data collected during this study is not currently planned to be shared outside the study team, in line with the current study plan. Anonymised, summary-level results may be published in medical journals or presented at conferences and shared with policymakers.

11. What Will Happen to the Results of the Study?

The results of this study will be published in a scientific medical journal and may be presented to doctors and health policymakers. You will not be identified in any report or publication. If you would like to know the overall results of the study once it is completed, please let the study team know, and arrangements will be made to inform you.

12. Who Is Organising and Funding This Research?

This study is being organised by Capital Development Authority (CDA) Hospital Islamabad. [Sponsor to confirm and insert funding source, if any.]

13. Who Has Reviewed This Study?

This study has been reviewed and approved by the Institute Research Board and Ethics Committee, CDA Hospital (Approval No. IRB-113-07-08-2025), to protect your safety, rights, and well-being.

14. Contact for Further Information

If you have any questions about this study, now or at any time during your participation, please contact:

Dr Fazal Rabbi, MD — Principal Investigator

Capital Development Authority (CDA) Hospital Islamabad

Telephone: +92 303 5646227

Email: faiz@bjmu.edu.cn

15. Statement of Consent

Please read the following statements. If you agree with them, and wish to take part, please sign and date this form.

- I confirm that I have read and understood the information sheet for the above study, and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, and without my medical care or legal rights being affected.
- I understand that my medical records may be looked at by responsible individuals from the study team, the sponsor, or regulatory authorities, where relevant to my participation in this study. I give permission for these individuals to access my records.
- I understand that the specific antibiotic used in my treatment will be chosen by my treating physician, and that only the planned duration of treatment (7 days or 14 days) will be determined by random assignment.
- I agree to take part in this study.

Participant's Name: _____

Signature: _____ Date: _____

Person Taking Consent (Name): _____

Signature: _____ Date: _____