

Role of rifaximin in acute pancreatitis

Submission date 06/09/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/09/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 10/09/2026	Condition category Digestive System	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Acute pancreatitis is an inflammation of the pancreas that can sometimes become serious and cause complications such as infection, organ failure and the need for intensive care. This study aimed to find out whether rifaximin, an antibiotic that mainly acts in the gut, could reduce these complications and improve recovery.

Who can participate?

Patients aged 18 years or above with acute pancreatitis who presented within 7 days of symptom onset

What does the study involve?

Participants received the usual treatment for acute pancreatitis. In addition, they were randomly assigned to receive either rifaximin 400 mg three times a day or a matching placebo tablet for 14 days. Neither the participant nor the treating study team knew which treatment had been given. Participants were followed during their hospital stay and for up to 90 days to assess their recovery, development of complications, and need for further treatment or procedures.

What are the possible benefits and risks of participating?

The potential benefit of participating in this study is that rifaximin may help reduce infectious complications and the need for interventions in patients with acute pancreatitis. The risks are expected to be minimal, as rifaximin is minimally absorbed from the gastrointestinal tract and therefore has limited systemic effects.

Where is the study run from?

Dayanand Medical College and Hospital (India)

When is the study starting and how long is it expected to run for?

May 2024 to March 2026

Who is funding the study?

Dayanand Medical College and Hospital (India); the placebo was provided by Appelon Pharma (India)

Who is the main contact?

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Contact information

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Additional identifiers

Study information

Scientific Title

Role of rifaximin in acute pancreatitis: a double-blind randomized placebo-controlled trial

Study objectives

Primary objective:

To compare the rate of composite infectious complications (infected pancreatic collections, bacteraemia, pneumonia, urosepsis, or infected ascites) at Day 30 between patients with acute pancreatitis receiving rifaximin 400 mg thrice daily versus placebo, in addition to standard medical therapy.

Secondary objectives:

1. To compare ICU stay duration, hospital stay duration, and 90-day mortality
2. To compare requirement for percutaneous catheter drainage and other interventional procedures
3. To compare rates of new-onset organ failure by Modified Marshall Score across serial timepoints
4. To compare antibiotic use in the first week and antifungal utilization
5. To perform severity-stratified analysis (mild/moderately severe/severe) of all primary and secondary outcomes
6. To identify independent predictors of adverse outcomes by multivariate logistic regression

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 22/04/2024, Research and Ethics Committee, Dayanand Medical College and Hospital (Dayanand Medical College and Hospital, Civil lines, Tagore Nagar, Ludhiana, 141001, India; +91 (0)9815555100; contact@dmch.edu), ref: DMCH/4/1012023(6993)

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Prevention

Study type(s)**Health condition(s) or problem(s) studied**

Acute pancreatitis

Interventions

Randomization:

Computer-generated randomization list. The randomization code was held by an independent pharmacist and was revealed only after database lock. Both the patients and treating team were blinded to treatment allocation. Allocation ratio: 1:1. Each patient was assigned a study /enrolment number sequentially at the time of enrolment.

Patients were allocated to either:

1. Rifaximin group: tablet Rifaximin 400 mg thrice daily (TID) for 14 days + standard treatment
2. Placebo group: matching placebo TID for 14 days + standard treatment

They were followed up until 90 days. Their demographic, etiological, clinical, biochemical and radiological profile are recorded and analysed.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Rifaximin

Primary outcome(s)

1. Composite infectious complications (infected pancreatic collection, bacteraemia, pneumonia, urosepsis, or infected ascites) measured using laboratory investigations (abdominal imaging, chest x-ray, blood and urine culture) at day 30

Key secondary outcome(s)

1. New onset organ failure measured using Modified Marshall Score (respiratory, renal and cardiovascular components) at day 7
2. Hospital stay duration (duration from admission to discharge or death) measured using hospital/medical records at discharge/death or Day 90
3. ICU stay duration measured using hospital/ICU records at discharge or Day 90
4. Need for intervention measured using hospital records documenting percutaneous catheter drainage and other interventional procedures at day 90
5. Survival rate measured using follow-up records/clinical follow-up for mortality status at day 90
6. Antibiotic utilization in week 1 measured using hospital medication/treatment records at first 7 days (week 1)
7. Antifungal utilization measured using hospital medication/treatment records at during the 90-day follow-up
8. Severity-stratified outcomes measured using comparison of primary and secondary outcomes after stratification into mild, moderately severe and severe AP at across the study follow-up (up to Day 90)
9. Composite adverse outcome (new-onset persistent organ failure, ICU requirement, or death), measured using hospital/ICU records (independent predictors identified by multivariable logistic regression as a secondary analysis) at day 90

Completion date

31/03/2026

Eligibility

Key inclusion criteria

1. Age >18 years
2. Acute pancreatitis (any etiology) with duration of onset <7 days at presentation
3. Patients willing to provide a written informed consent

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

70 Years

Sex

All

Total final enrolment

120

Key exclusion criteria

1. Age <18 years
2. Presence of infective infections complications before randomization (urinary tract infection [UTI]/cholangitis/lower respiratory tract infection [LRTI]/positive blood culture/high procalcitonin >0.5 ng/ml)
3. Pregnancy
4. Malignancy
5. Refusal to consent for enrolment into the study
6. Prior rifaximin use within 4 weeks of enrolment
7. Known hypersensitivity to rifamycin antibiotics
8. Inability to take oral medications
9. Renal replacement therapy at enrolment

Date of first enrolment

07/05/2024

Date of final enrolment

31/12/2025

Locations

Countries of recruitment

India

Sponsor information

Organisation

Dayanand Medical College & Hospital

ROR

<https://ror.org/005fgpm31>

Funder(s)

Funder type

Funder Name

Dayanand Medical College & Hospital

Funder Name

Appellon Pharma

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available