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A trial to assess if aspirin with omega-3 and colchicine are medicines that can help recovery from a COPD exacerbation.

Submission date 19/12/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 24/02/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 27/07/2026	**Condition category** Respiratory	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a common condition. People living with COPD often experience worsening of symptoms that cause them to become very unwell. These worsening symptoms are called exacerbations or flare-ups of COPD. They are a leading cause of emergency hospital admissions.
Treatments for COPD flare-ups have not changed over decades. There is an urgent need to improve treatments.
We aim to find out if aspirin plus an omega-3; and low dose colchicine; may improve recovery from a COPD flare-up, and reduce complications of flare-ups.

Who can participate?
We will recruit about 440 people experiencing a COPD flare-up; both from GP practices and hospitals across the UK.

What does the study involve?
In addition to standard of care treatment of a flare-up, participants will be randomly (by chance) allocated to one of these trial arms:
1) control arm (placebo)
2) aspirin plus omega-3
3) colchicine
4) aspirin plus omega-3 and colchicine

Participants will be on trial treatment for 3 months.
Both the participant and their trial team will not know which of the trial treatment arms they are randomised to. We will be able to do this by using dummy pills (called placebo) matched to active treatments.

There are 3 trial visits: baseline, 1 month and 3 months. There is also a telephone follow up at 2 weeks, 6 months and 12 months.
Participants will be asked to complete a diary for up to 3 months and to let us know if any flare-ups. There will be a blood sample at baseline to assess routine labs and at 1 and 3 months.

What are the possible benefits and risks of participating?
There is no guarantee that you will benefit from taking part in this trial. You may recover quicker from a flare-up of COPD and experience relief in your relief in your symptoms, an improvement in your COPD, or possible cardiovascular benefits. Additionally, the information collected as part of your participation in this trial may benefit people with COPD in the future.

We have tried to minimise potential burden of taking part in the trial by enabling participants to take part remotely where possible and rationalise the number of visits/consultations, for example week 2 is a phone call only.

There are a few blood tests-at baseline and follow up, and again the number of blood tests /venepuncture is the minimum needed to answer the research questions of the trial.

All drugs have benefits but also potential risks or side effects and we are testing medications in this trial for efficacy. This trial uses licensed medications (outside their indication) with well-recognised established side effect profile, using safely as common medications in use.

For example, for low dose aspirin (75mg) we have enabled co-administration of a proton pump inhibitor (PPI) if considered higher risk for side effects of aspirin, and excluded participants who are at high risk of bleeding. For colchicine, we are using an extremely low dose (lower than the large stroke, cardiovascular trials) of 500mcg alternate day dosing, aware that elderly people have a slower metabolism of drugs.

We have follow up mechanisms in the trial to monitor efficacy, safety and tolerability and enable participants to stop trial medication whenever they want to.
Each participant is given a trial card and a Participant Information Sheet with their contact team details.

Where is the study run from?
Cambridge Clinical Trials Unit (CCTU) (UK)

When is the study starting and how long is it expected to run for?
July 2026 to August 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
cuh.easecopd@nhs.net

Contact information

Type(s)
Principal investigator

Contact name

Dr Marie Fisk

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Type(s)
Public, Scientific

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None - EASE-COPD Central Trial Coordinator

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Additional identifiers

Integrated Research Application System (IRAS)
1010119

Central Portfolio Management System (CPMS)
58327

Study information

Scientific Title
A factorial randomised placebo controlled double-blind trial to evaluate Efficacy and safety of adding ASpirin plus omEga-3 and colchicine as repurposed treatments to enhance COPD exacerbation resolution and reduce recurrent exacerbations (EASE-COPD)

Acronym
EASE-COPD

Study objectives
To evaluate the efficacy of adding low dose aspirin plus omega-3, and colchicine, to standard of care treatment for a COPD exacerbation.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 06/02/2026, Seasonal REC (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8241; seasonal.rec@hra.nhs.uk), ref: 26/LO/0070

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Factorial

Purpose
Treatment

Study type(s)
Efficacy, Safety, Not Specified

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
2x2 factorial design trial. Participants will be randomised to of the following:
1. Aspirin 75mg with 1g omega-3 once daily; +placebo colchicine 500mcg every other day (alternate days) for 12 weeks.
2. Colchicine 500mcg every other day; + placebo aspirin 75mg with placebo 1g omega 3 once daily for 12 weeks.
3. Aspirin 75mg with 1g omega-3 once daily; +colchicine 500mcg every other day for 12 weeks
4. Placebo colchicine 500mcg every other day; + placebo aspirin 75mg with placebo 1g omega 3 once daily for 12 weeks.

Sealed Envelope Ltd (https://www.sealedenvelope.com/) used for randomisation system.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Aspirin, Colchicine, Omega-3-acid ethyl esters 90

Primary outcome(s)
1. Incident of treatment failure up to 12 weeks from starting standard of care treatment of COPD: Treatment failure is composite of requirement of re-treatment of a COPD exacerbation (i.

e; oral corticosteroids and/or oral antibiotics), hospitalisation from any cause, or death, measured using patient report and/or using data collected from the patient’s medical records at 2, 4 and 12 weeks

Key secondary outcome(s)

1. Respiratory symptoms measured using the COPD Assessment Test (CAT), Visual Analogue Scale (VAS), Breathlessness, Cough, and Sputum Scale (BCSS) and the Modified Medical Research Council Dyspnea Scale (mMRC) scoring at baseline, 2, 4 and 12 weeks

2. Duration from COPD exacerbation onset to participant recovery measured using patient report and/or using data collected from the patient’s medical records at 2, 4 and 12 weeks

3. Time to treatment failure from starting standard of care treatment of COPD until week 12 measured using patient report and/or using data collected from the patient’s medical records at 2, 4, and 12 weeks

4. Number, rate and severity of exacerbations and time to next exacerbation during the first 12 weeks measured using patient report and/or using data collected from the patient's medical records on the requirement of additional steroids and/or antibiotics to treat an exacerbation at 2, 4 and 12 weeks

5. Length of exacerbation-free status in the trial during the first 12 weeks, where there was no requirement for further use of steroids and/or antibiotics to treat an exacerbation, measured using patient report an/or using data collected from the patients' medical records at 2, 4 and 12 weeks

6. Cardiovascular events measured using patient report and/or using data collected from the patient's medical records at 2, 4 and 12 weeks

7. Mortality measured using medical records at 2, 4 and 12 weeks

8. Hospitalisation measured using patient report and/or patient's medical records at baseline, 2, 4 and 12 weeks

9. Healthcare usage during the first 12 weeks measured using patient report and/or patient's medical records on hospitalisation, GP attendance, urgent care use and emergency service telephone use at baseline, 2, 4 and 12 weeks

10. Participant reported adherence and tolerability measured using a Likert scale at baseline, 2, 4 and 12 weeks

11. Adverse events of special interest and serious adverse reactions from baseline up to 12 weeks measured using patient report and/or patient's medical records, reviewed at the scheduled visits at 2, 4 and 12 weeks

Completion date

01/08/2029

Eligibility

Key inclusion criteria

1. Be willing and able to give consent to participate
2. Individuals with a COPD exacerbation
3. Aged 40 years and older
4. In the Investigator's opinion, willing and able to comply with trial requirements

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Inability to take the trial medication
2. Allergy or unsuitable for trial medications, including hypersensitivity or allergy to any of the trial drugs: aspirin, colchicine, omega-3, salicylic acid compounds, or prostaglandin synthetase inhibitors or excipients (including allergy to peanuts or soya \[lecithin], gelatine, glycerol, fish). Please see Trial Procedures Manual (TPM) for full list of excipients
3. Diagnosis of aspirin/NSAID-induced asthma (diagnosis of asthma itself is not an exclusion criterion)
4. Patients diagnosed with rare hereditary problems of galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption, as medicine contains lactose
5. Already taking aspirin and/or colchicine, antiplatelets^, warfarin; concurrent treatment with systemic oral carbonic anhydrase inhibitors (acetazolamide), oral uricosuric drugs (e.g., probenecid, sulfinpyrazone), P-glycoprotein (P-gp) inhibitors or moderate-strong CYP 3A4 inhibitors (macrolides, diltiazem, verapamil, azoles, ritonavir, ciclosporin), methotrexate use (>15 mg/week).
6. Women of childbearing potential (WoCBP)+, unless using effective measures of contraception; pregnancy, planned pregnancy during the trial (52 weeks), breastfeeding
7. Any medical history or clinically relevant abnormality that makes the patient ineligible for inclusion in the trial because of a safety concern relating to participating in the trial or trial medications
8. Progressive neuromuscular disorder, myositis, myopathy, raised CK on statins
9. Participant with life expectancy of less than 3 months
10. Known immunocompromise, defined as a diagnosed immunodeficiency disorder (e.g., HIV-1 or HIV-2) or regular use of systemic immunosuppressive therapy (excluding physiologic replacement doses of hydrocortisone or prednisolone for adrenal insufficiency, which are permitted)
11. Clinically significant renal impairment, including haemodialysis or filtration use, eGFR <50 ml /min and/or serum creatinine >150 mmol/L

12. Clinically significant hepatic impairment, including presence of liver cirrhosis, ascites, encephalopathy, Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level that is persistently ≥1.5 times the upper limit of normal
13. Blood dyscrasia (i.e., leukopenia \[WCC <4.0 x10⁹/L*], thrombocytopenia \[<110 x10⁹/L], anaemia \[Hb <110 g/L]). *Drop in WCC may occur with an intercurrent viral exacerbation. Rescreening of blood results is permitted as values are often variable
14. Patients with current or historical conditions that significantly increase bleeding risk, including active bleeding, prior major haemorrhage (e.g., cerebrovascular or gastrointestinal, gastroduodenal ulcer, gastroduodenal perforation due to ulceration), coagulation disorders (e.g., haemophilia, thrombocytopenia)
15. Current participation in another clinical trial of investigational medicinal product (CTIMP) or intervention
16. Patients whose increased respiratory symptoms are primarily attributable to an alternative diagnosis (e.g., pneumonia, ongoing sepsis, pulmonary embolism, pneumothorax, acute cardiovascular event such as ACS or heart failure) rather than an acute exacerbation of COPD

Date of first enrolment
23/07/2026

Date of final enrolment
31/03/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Sponsor information

Organisation
Cambridge Clinical Trials Unit (CCTU)

Funder(s)

Funder type

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The Trial Management Group will review any reasonable requests for data for research purposes, following completion of the trial; i.e.; once the trial report has been completed and published and the primary paper published. If data is to be shared, a contract with the Sponsor must be executed prior to any data sharing. Any export will be de-identified and the necessary data fields/variables to answer the research question(s) only. Each export will be accompanied by a data dictionary. Following completion of the project, anonymised data will be shared upon reasonable request to the CI.

IPD sharing plan summary
Available on request