

Phase II trial: ETH47-201

Submission date 23/05/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/06/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/06/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended

Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1011224

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

ETH47-201

Study information

Scientific Title

Phase II trial: ETH47-201

Study objectives

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Ethics approval required

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Ethics approval(s)

Approved 14/02/2025, Wales 3 REC (Wales Research Ethics Committee 3, Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2922 941107; Wales.REC3@wales.nhs.uk), ref: 25/WA/0013

Study design

Phase II double-blind randomized placebo-controlled study in 50 volunteers with asthma

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Drug

Pharmaceutical study type(s)

Other - The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Phase

Phase II

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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Overall study start date

15/11/2024

Completion date

12/05/2026

Eligibility

Key inclusion criteria

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Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

50

Key exclusion criteria

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Date of first enrolment

09/06/2025

Date of final enrolment

12/05/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Imperial College Respiratory Research Unit
Imperial College Healthcare NHS Trust
Mint Wing
South Wharf Road
St Mary's Hospital
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United Kingdom
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Sponsor information

Organisation

Ethris GmbH

Sponsor details

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Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Ethris GmbH

Results and Publications

Publication and dissemination plan

Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this Phase II study. Results may be posted on or after the date of publication of full trial details.

Intention to publish date

12/11/2028

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non-therapeutic clinical trials

IPD sharing plan summary

Not expected to be made available