

Phase II trial code: 1066

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
07/08/2025	Recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
10/12/2025	Deferred	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
21/01/2026	Respiratory	<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

Type(s)

Scientific

Contact name

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Type(s)

Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)
2025-522359-24-00

Integrated Research Application System (IRAS)
1011840

Protocol serial number
1066

Central Portfolio Management System (CPMS)
67199

Study information

Scientific Title
Phase II trial code: 1066

Study objectives

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Ethics approval required
Ethics approval required

Ethics approval(s)

approved 08/10/2025, Seasonal REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8241; seasonal.rec@hrs.nhs.uk), ref: 25/LO/0628

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
-

Study type(s)

Efficacy, Safety

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

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Key secondary outcome(s)

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Completion date

31/12/2027

Eligibility

Key inclusion criteria

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Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

40 years

Upper age limit

85 years

Sex

All

Total final enrolment

0

Key exclusion criteria

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Date of first enrolment

31/08/2025

Date of final enrolment

31/03/2027

Locations

Countries of recruitment

United Kingdom

Denmark

Netherlands

Spain

Study participating centre

-

-

NO COUNTRY SPECIFIED, assuming England

England

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Sponsor information

Organisation
University of Leicester

ROR
<https://ror.org/04h699437>

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics, AZ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date