ISRCTN35638452 https://doi.org/10.1186/ISRCTN35638452

Phase II trial code: 1066

Submission date 07/08/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 10/12/2025	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 10/12/2025	**Condition category** Respiratory	[_] Individual participant data [X] 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

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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

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))
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.

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
-

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