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Deferred registration: Fortrea code: 783991

Submission date 03/11/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 03/11/2026	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 03/11/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date

Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
1014630

Study information

Scientific Title
Deferred registration: Fortrea code: 783991 [Full scientific title to be added on or before the deferral expiry date]

Study objectives

This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/09/2026, East of England - Cambridge Central Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)2071048285; cambridgecentral.rec@hra.nhs.uk), ref: 26/EE/0183

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Single

Purpose
Absorption, metabolism and excretion (AME)

Study type(s)

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome(s)

1. [Outcome name] measured using [Metric or method of measurement] at [Timepoint(s)]. This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date

Key secondary outcome(s)

Completion date
27/07/2027

Eligibility

Key inclusion criteria
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Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
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Date of first enrolment
02/11/2026

Date of final enrolment
27/07/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Fortrea Clinical Research Unit
Drapers Yard, Marshall St, Holbeck
Leeds
England
LS11 9EH

Sponsor information

Organisation
Lundbeck (Denmark)

ROR
https://ror.org/0564cd633

Funder(s)

Funder type

Funder Name
H. Lundbeck A/S

Alternative Name(s)
Lundbeck

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Denmark

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available