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Deferred registration: Fortrea code: 776181

Submission date 08/07/2026	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 09/07/2026	**Overall study status** Deferred	
Last Edited 02/10/2026	**Condition category** Other	

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)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1013923

Study information

Scientific Title
Deferred registration: Fortrea code: 776181 [Full scientific title to be added on or before the deferral expiry date]

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/06/2026, East of England - Cambridge Central Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; N/A; cambridgecentral.rec@hra.nhs.uk), ref: 26/EE/0100

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Pharmacokinetic

Study type(s)

Health condition(s) or problem(s) studied
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

Interventions
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

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
1. 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. [Outcome] measured using [measure] at [timepoint]

Key secondary outcome(s)

Completion date
20/11/2026

Eligibility

Key inclusion criteria
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

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
0 Years

Upper age limit
1 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
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Date of first enrolment
15/07/2026

Date of final enrolment
03/11/2026

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