ISRCTN17866568 https://doi.org/10.1186/ISRCTN17866568

Deferred registration: Fortrea code: 780587

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

Plain English summary of protocol
The Health Research Authority has approved a deferral. 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)
1013458

Study information

Scientific Title
Deferred registration: Fortrea code: 780587
Full scientific title to be added on or before the deferral expiry date

Study objectives

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Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/03/2026, London - Brent Research Ethics Committee (Health Research Authority 2 Redman Place Stratford, London, E20 1JQ, United Kingdom; no telephone number provided; brent.rec@hra.nhs.uk), ref: 26/LO/0019

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Metabolism and bioavailability

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] measured using [measure] at [timepoint]. The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date.

Key secondary outcome(s)

Completion date
20/07/2027

Eligibility

Key inclusion criteria
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Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
35 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date.

Date of first enrolment
08/07/2026

Date of final enrolment
14/08/2026

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