

# Deferred registration: Fortrea code: 776181

<b>Submission date</b> 08/07/2026	<b>Recruitment status</b> Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/07/2026	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/07/2026	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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)

Public, Scientific, Principal investigator

### Contact name

Dr Firas Almazedi

### Contact details

Drapers Yard, Marshall St, Holbeck  
Leeds  
United Kingdom  
LS11 9EH  
+441133013642  
firas.almazedi@fortrea.com

## 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)**

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

### **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

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

### Date of first enrolment

15/07/2026

### Date of final enrolment

09/10/2026

## 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