

# Phase I trial: Parexel International Ltd. Code: 20628A

|                                        |                                                   |                                                                                                                         |
|----------------------------------------|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>17/07/2026   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                                  |
| <b>Registration date</b><br>21/07/2026 | <b>Overall study status</b><br>Deferred           | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>21/07/2026       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> 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)

Principal investigator, Public, Scientific

### Contact name

Dr Pablo Forte Soto

### Contact details

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## Additional identifiers

### Integrated Research Application System (IRAS)

1011008

### Sponsor code

20628A

# Study information

## Scientific Title

Phase I trial: Parexel International Ltd. Code: 20628A

## Study objectives

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.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

Approved 27/01/2025, South Central - Berkshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8276; berkshireb.rec@hra.nhs.uk), ref: 24/SC/0334

## Primary study design

Interventional

## Allocation

Randomized controlled trial

## Masking

Blinded (masking used)

## Control

Placebo

## Assignment

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## Purpose

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## Study type(s)

## Health condition(s) or problem(s) studied

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## Interventions

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.

**Intervention Type**

Not Specified

**Primary outcome(s)**

1. [Outcome] measured using [measure] at [timepoint]. 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.

**Key secondary outcome(s)****Completion date**

08/07/2026

## Eligibility

**Key inclusion criteria**

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**Healthy volunteers allowed**

Yes

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

55 Years

**Sex**

All

**Total final enrolment**

78

**Key exclusion criteria**

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**Date of first enrolment**

19/02/2025

**Date of final enrolment**

15/06/2026

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Parexel Early Phase Clinical Unit**

Northwick Park Hospital

Harrow

England

HA1 3UJ

## **Sponsor information**

**Organisation**

H. Lundbeck A/S

## **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