

Deferred registration: Fortrea code: 782153

Submission date 20/07/2026	Recruitment status Recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/07/2026	Overall study status Deferred	☐ Statistical analysis plan ☐ Results
Last Edited 21/07/2026	Condition category Other	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

The sponsor has requested a 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 Somasekhara Menakuru

Contact details

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Additional identifiers

Integrated Research Application System (IRAS)

1013670

Study information

Scientific Title

Deferred registration: Fortrea code: 782153

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 02/07/2026, 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/0132

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Single

Purpose

Pharmacokinetics

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 sponsor has requested a deferral. The full details will be added to the trial record on or before the deferral expiry date

Key secondary outcome(s)

Completion date

20/04/2027

Eligibility

Key inclusion criteria

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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

20/07/2026

Date of final enrolment

20/04/2027

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
Roche (Switzerland)

ROR
<https://ror.org/00by1q217>

Funder(s)

Funder type

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available