

Phase I trial: Fortrea Clinical Pharmacology Services 1006539

Submission date 06/12/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/12/2022	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/07/2025	Condition category Other	<input type="checkbox"/> Individual participant data <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)

Public, Scientific, Principal Investigator

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1006539

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 1006539

Study information

Scientific Title

Phase I trial: Fortrea Clinical Pharmacology Services 1006539

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

Old ethics approval format

Ethics approval(s)

Approved 24/11/2022, North East – York Research Ethics Committee, NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0)207 104 8079; york.rec@hra.nhs.uk; ref: 22/NE/0204.

The HRA has approved deferral of publication of trial details.

Study design

First-in-man safety, pharmacokinetics and pharmacodynamics trial in 106 healthy volunteers.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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Secondary outcome measures

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Overall study start date

03/10/2022

Completion date

04/06/2024

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

106

Key exclusion criteria

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Date of first enrolment

06/12/2022

Date of final enrolment

03/05/2024

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Fortrea Clinical Research Unit Limited

Draper's Yard Marshall Street

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Sponsor information**Organisation**

Idorsia Pharmaceuticals Ltd

Sponsor details

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Sponsor type

Industry

Website

<https://www.idorsia.com>

Funder(s)

Funder type

Industry

Funder Name

Idorsia Pharmaceuticals Ltd

Results and Publications

Publication and dissemination plan

Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this phase I study and the negligible benefit to the public of phase I information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date

04/12/2026

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No