

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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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1006539

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 1006539

Study information

Scientific Title
Phase I trial: Fortrea Clinical Pharmacology Services 1006539

Study objectives
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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

Study type(s)
Treatment

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)

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Key secondary outcome(s)

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Completion date

04/06/2024

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Fortrea Clinical Research Unit Limited

Draper's Yard Marshall Street

Holbeck

Leeds

United Kingdom

LS11 9EH

Sponsor information

Organisation

Idorsia Pharmaceuticals Ltd

Funder(s)

Funder type

Industry

Funder Name

Idorsia Pharmaceuticals Ltd

Results and Publications

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