ISRCTN28892128 https://doi.org/10.1186/ISRCTN28892128

Phase I trial: Fortrea Clinical Pharmacology Services 1006539

Submission date 06/12/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/12/2022	**Overall study status** Deferred	
Last Edited 19/01/2026	**Condition category** Other	

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

Integrated Research Application System (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)
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))
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.

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

Total final enrolment
0

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
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England
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

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