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 16/07/2025	**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

Contact name
Dr Clinical Trials Information

Contact details
Hegenheimermattweg 91
Allschwil
Switzerland
4123
+41 58 844 1977
idorsiaclinicaltrials@idorsia.com

Type(s)
Principal Investigator

Contact name
Dr Jim Bush

Contact details
Fortrea Clinical Research Unit Ltd
Drapers Yard
Marshall Street
Holbeck

Leeds
United Kingdom
LS11 9EH
+44 113 394 5200
jim.bush@fortrea.com

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
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.

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
Drug

Phase
Phase I

Drug/device/biological/vaccine name(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.

Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
03/10/2022

Completion date
04/06/2024

Eligibility

Key inclusion criteria
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.

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
106

Key exclusion criteria
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.

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
Holbeck
Leeds
United Kingdom
LS11 9EH

Sponsor information

Organisation
Idorsia Pharmaceuticals Ltd

Sponsor details

Hegenheimermattweg 91
Allschwil
Switzerland
4123
+41 58 844 1977
idorsiaclinicaltrials@idorsia.com

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