

# Phase I trial: Fortrea Clinical Pharmacology Services 1006539

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
06/12/2022	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
07/12/2022	Deferred	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
19/01/2026	Other	<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

### Contact name

Dr Clinical Trials Information

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### Type(s)

Principal investigator

### Contact name

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### Contact details

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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

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

### 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

**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

Holbeck

Leeds

England

LS11 9EH

## Sponsor information

**Organisation**

Idorsia Pharmaceuticals Ltd

## Funder(s)

**Funder type**

Industry

**Funder Name**

## 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No