

Phase 1 Trial: Fortrea

Submission date 26/06/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/06/2024	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/06/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input 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

Contact name

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Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1006698

Protocol serial number

IRAS 1006698

Study information

Scientific Title

Phase 1 Trial: Fortrea

Study objectives

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Ethics approval required

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Ethics approval(s)

1. approved 19/01/2023, London-Brent Research Ethic Committee (80 London Road, Skipton House, London, SE1 6LH, United Kingdom; +44 (0)20 3080 6456; brent_rec@hra.nhs.uk), ref: 22/LO/0850

2. approved 07/03/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6456; clintrialhelpline@mhra.gov.uk), ref: CTA 36772/0031/001-0001

Study design

Phase I safety tolerability and pharmacokinetics in 96 healthy volunteers

Primary study design

Interventional

Study type(s)

Safety

Health condition(s) or problem(s) studied

Healthy volunteers

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

12/01/2024

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

18/04/2023

Date of final enrolment

12/01/2024

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

JAZZ Pharmaceuticals Research UK Ltd

Funder(s)

Funder type

Not defined

Funder Name

JAZZ Pharmaceuticals Research UK 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 and the negligible benefit to the public of publication of results of nontherapeutic clinical trials.

IPD sharing plan summary

Not expected to be made available