ISRCTN40371122 https://doi.org/10.1186/ISRCTN40371122

Phase 1 Trial: Fortrea

Submission date
26/06/2024

Recruitment status
No longer recruiting

Registration date
27/06/2024

Overall study status
Deferred

Last Edited
27/06/2024

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1006698

Study information

Scientific Title
Phase 1 Trial: Fortrea

Study objectives
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Ethics approval required
Ethics approval required

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)
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
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