ISRCTN22812347 https://doi.org/10.1186/ISRCTN22812347

Phase I trial: Fortrea Phase I unit Leeds

Submission date 09/01/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 10/01/2025	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 10/01/2025	**Condition category** Other	[_] Individual participant data [X] 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.

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Additional identifiers

EudraCT/CTIS number
2024-000381-25

IRAS number
1009954

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1009954 Fortrea Phase I unit Leeds

Study information

Scientific Title
Phase I trial: Fortrea Phase I unit Leeds [The full scientific title will be published within 30 months after the end of the trial]

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/11/2024, North East-York (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8079; york.rec@hra.nhs.uk), ref: 24/NE/0138

Study design
Human AME trial in 6 healthy volunteers and 6 iron-overloaded patients

Primary study design
Interventional

Secondary study design

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Treatment

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacodynamic

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
29/09/2024

Completion date
27/02/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Sex
Both

Target number of participants
12

Key exclusion criteria
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Date of first enrolment
28/11/2024

Date of final enrolment
12/02/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Fortrea Phase I unit
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Sponsor information

Organisation
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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Pharmacosmos

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 may be posted on or after the date of publication of full trial details.

Intention to publish date

01/06/2026

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 and the negligible benefit to the public of publication of results of non-therapeutic clinical trials.

IPD sharing plan summary

Not expected to be made available