

Phase I trial: Fortrea Phase I unit Leeds

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
09/01/2025	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
10/01/2025	Deferred	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
10/01/2025	Other	<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)

Principal investigator

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2024-000381-25

Integrated Research Application System (IRAS)
1009954

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

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

27/02/2025

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer, Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre**Fortrea Phase I unit**

Drapers Yard

Marshall Street

Leeds

United Kingdom

LS 11 9EH

Sponsor information

Organisation

Pharmacosmos (Denmark)

ROR

<https://ror.org/04g1gk322>

Funder(s)

Funder type

Industry

Funder Name

Pharmacosmos

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 non-therapeutic clinical trials.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes