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.

Contact information

Type(s)
Principal investigator

Contact name
Dr Jim Bush

Contact details
Fortrea Clinical Research Unit Ltd
Drapers Yard
Marshall St
Holbeck
Leeds
United Kingdom
LS11 9EH
+44 (0)1133013590
ukirelandregethics@fortrea.com

Type(s)
Scientific

Contact name
Mr Clinical Scientist

Contact details
Roervangsvej, 30
Holbaek
Denmark

4300
+45 (0)59 48 59 59
info@pharmacosmos.com

Type(s)
Public

Contact name
Mr Head Of Clinical Development

Contact details
Roervangsvej 30
Holbaek
Denmark
4300
+45 (0)59 48 59 59
info@pharmacosmos.com

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)
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
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