Phase 1 trial: Fortrea CRU code: 8526072

Submission date	Recruitment status	Prospectively registered
04/08/2025	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
04/08/2025	Deferred	Results
Last Edited	Condition category	Individual participant data
04/08/2025	Other	[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

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Type(s)

Public, Scientific

Contact name

Dr. Project Management Department

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1009878

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Phase 1 trial: Fortrea CRU code: 8526072

Acronym

Nil known

Study objectives

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Ethics approval required

Ethics approval required

Ethics approval(s)

approved 30/10/2024, North East REC – York (2 Redman Place, London, E20 1JQ, United Kingdom; +44 207 104 8052; york.rec@hra.nhs.uk), ref: 24/NE/0157

Study design

Interventional

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

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Interventions

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.

Intervention Type

Other

Primary outcome(s)

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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

02/03/2025

Eligibility

Key inclusion criteria

Healthy human volunteer

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

29/01/2025

Date of final enrolment

04/02/2025

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

CellCentric Limited

Funder(s)

Funder type

Industry

Funder Name

CellCentric Limited

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 publication of results of non-therapeutic clinical trials.

IPD sharing plan summary

Not expected to be made available