ISRCTN60181900 https://doi.org/10.1186/ISRCTN60181900

Phase 1 trial: Fortrea CRU code: 8526072

Submission date 04/08/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 04/08/2025	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 04/08/2025	**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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1009878

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

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 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
23/12/2023

Completion date
02/03/2025

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
8

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
England

United Kingdom

Study participating centre
Fortrea Clinical Research Unit Limited
Draper's Yard Marshall Street
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Sponsor information

Organisation
CellCentric Limited

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
CellCentric Limited

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

Intention to publish date
02/03/2026

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 publication of results of non-therapeutic clinical trials.

IPD sharing plan summary
Not expected to be made available