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A Phase 1 trial: Fortrea Phase 1 Leeds Clinic: SUDO-550-101

Submission date	Recruitment status	[ ] Prospectively registered
02/07/2025	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/07/2025	Deferred	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/08/2025	Other	[ ] 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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Additional identifiers

Integrated Research Application System (IRAS)
1010113

Protocol serial number
8535365

Study information

Scientific Title
A Phase 1 trial: Fortrea Phase 1 Leeds Clinic: SUDO-550-101

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/09/2024, London Chelsea Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8141; chelsea.rec@hra.nhs.uk), ref: 24/LO/0575

Primary study design
Interventional

Study design
Interventional single-centre partially blinded randomized study

Study type(s)
Safety

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
20/08/2025

Eligibility

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
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Date of first enrolment
03/10/2024

Date of final enrolment
20/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Fortrea Clinical Research Unit Limited
Draper's Yard Marshall Street
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Leeds
United Kingdom
LS11 9EH

Sponsor information

Organisation
Sudo Biosciences Limited

Funder(s)

Funder type
Industry

Funder Name
Sudo Biosciences 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 public of publication of results of non-therapeutic clinical trials.

IPD sharing plan summary
Not expected to be made available