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

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

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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1010113

ClinicalTrials.gov (NCT)
Nil known

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

Study design
Interventional single-centre partially blinded randomized study

Primary study design
Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied

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Interventions
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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
Holbeck
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