ISRCTN13177674 https://doi.org/10.1186/ISRCTN13177674

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

EudraCT/CTIS number
Nil known

IRAS number
1010113

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
8535365

Study information

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

Study objectives
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.

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

Secondary study design
Randomised parallel trial

Study setting(s)

Other

Study type(s)
Safety

Participant information sheet
Not available in web format, please use the contact details to request a 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
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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
01/07/2024

Completion date
20/08/2025

Eligibility

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

Age group
Adult

Sex
Both

Target number of participants
165

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
England

United Kingdom

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

Sponsor information

Organisation
Sudo Biosciences Limited

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Sponsor type
Industry

Website
https://www.sudobio.com/

Funder(s)

Funder type
Industry

Funder Name
Sudo Biosciences 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 may be posted on or after the date of publication of full trial details.

Intention to publish date
20/02/2028

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