ISRCTN10327687 https://doi.org/10.1186/ISRCTN10327687

A Phase 1 trial: MEU Phase 1 Clinic: SUDO-286-102

Submission date 05/09/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/09/2025	**Overall study status** Deferred	
Last Edited 08/09/2025	**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
1006866

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A Phase 1 trial: MEU Phase 1 Clinic: SUDO-286-102

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 20/06/2024, North West - Greater Manchester Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048023; gmcentral.rec@hra.nhs.uk), ref: 24/NW/0062

Study design
Interventional single-centre blinded randomized study

Primary study design
Not Specified

Secondary study design

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Safety

Participant information sheet
Not available in web format, please use 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
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
03/05/2024

Completion date
17/04/2025

Eligibility

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

Age group
Adult

Sex
Both

Target number of participants

Key exclusion criteria
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Date of first enrolment
20/06/2024

Date of final enrolment
18/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Medicines Evaluation Unit Limited
The Langley Building
Southmoor Road
Wythenshawe
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Sponsor information

Organisation
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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Sudo Biosciences

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

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