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

Type(s)
Principal investigator

Contact name
Dr Naimat Khan

Contact details
The Langley Building
Wythenshawe Hospital
Manchester
United Kingdom
M23 9QZ
+44 (0)161 946 4050
MKhan@meu.org.uk

Type(s)
Public, Scientific

Contact name
Dr Ian Mills

Contact details
Sudo Biosciences Limited, 3rd Floor, 1 Ashley Road
Altrincham
United Kingdom

WA14 2DT
-
imills@sudobio.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1006866

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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
Other

Study type(s)
Safety

Health condition(s) or problem(s) studied
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.

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)
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.

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
17/04/2025

Eligibility

Key inclusion criteria
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.

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
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.

Date of first enrolment
20/06/2024

Date of final enrolment
18/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Medicines Evaluation Unit Limited
The Langley Building
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9QZ

Sponsor information

Organisation
Sudo Biosciences

Funder(s)

Funder type
Industry

Funder Name
Sudo Biosciences

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes