ISRCTN16822084 https://doi.org/10.1186/ISRCTN16822084

Phase I Trial: 36414 (SUDO-550-102)

Submission date 16/01/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 16/01/2026	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 16/01/2026	**Condition category** Other	[_] Individual participant data [X] 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)
Public, Scientific

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Additional identifiers

Study information

Scientific Title
Phase I Trial: 36414 (SUDO-550-102)

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 20/11/2025, Wales Research Ethics Committee 2 (Health and Care Research Wales, Floor 4, Crown Building, Cathays Park, Cardiff, CF10 3NQ, United Kingdom; N/A; Wales. REC2@wales.nhs.uk), ref: 25/WA/0247

2. approved 01/12/2025, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; N/A; info@mhra.gov.uk), ref: CTA 59625/0003/001-0001

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
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Study type(s)

Health condition(s) or problem(s) studied
N/A - healthy volunteers

Interventions

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Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
1. 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. measured using - at -

Key secondary outcome(s))

Completion date
09/03/2026

Eligibility

Key inclusion criteria
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Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
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Date of first enrolment
08/12/2025

Date of final enrolment
08/02/2026

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Simbec-Orion Clinical Pharmacology (AKA Simbec Research Ltd)
Simbec-Orion Clinical Pharmacology, Merthyr Tydfil Industrial Park, Cardiff Road
Merthyr Tydfil
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CF48 4DR

Sponsor information

Organisation
Sudo Biosciences Ltd

Funder(s)

Funder type

Funder Name
Sudo Biosciences Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available