

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

Submission date 16/01/2026	Recruitment status No longer 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 ☒ 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

Contact name

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Type(s)

Principal investigator

Contact name

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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

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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

Wales

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