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Phase I Trial: 36676 (P2-101-301P)

Submission date 04/08/2025	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 04/08/2025	**Overall study status** Deferred	
Last Edited 04/08/2025	**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

Type(s)
Public, Scientific

Contact name
Dr Lynn Howard

Contact details
Phase Pharmaceuticals LLC
9425 Lenel Pl
Dallas
United States of America
TX 75220
+1 (0)917 683 1240
lynn@phasepharma.com

Type(s)
Principal Investigator

Contact name
Dr Annelize Koch

Contact details
Simbec-Orion Clinical Pharmacology
Merthyr Tydfil Industrial Park
Cardiff Road
Merthyr Tydfil
United Kingdom

CF48 4DR
+44 (0)1443694313
annelize.koch@simbecorion.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1012438

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
P2-101-301P

Study information

Scientific Title
Phase I Trial: 36676 (P2-101-301P)

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 14/07/2025, Wales Research Ethics Committee 2 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2922 941119; Wales.REC2@wales.nhs.uk), ref: 25.WA.0172

2. Approved 21/07/2025, MHRA (MHRA, 10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 59180/0001/001-0001

Study design
Two-way crossover trial in up to 12 participants with known peanut hypersensitivity

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Other, Safety, Efficacy

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
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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacodynamic

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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Secondary outcome measures
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Overall study start date
12/05/2025

Completion date
03/11/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
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Date of first enrolment
05/08/2025

Date of final enrolment
20/10/2025

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Simbec Research Limited
Simbec House Merthyr Tydfil Industrial Park
Merthyr Tydfil Industrial Park
Pentrebach
Merthyr Tydfil

Mid Glamorgan
United Kingdom
CF48 4DR

Sponsor information

Organisation
Phase Pharmaceuticals LLC

Sponsor details
9425 Lenel Pl
Dallas
United States of America
TX 75220
+1 (0)917 683 1240
info@phasepharma.com

Sponsor type
Industry

Website
https://phasepharma.com/

Funder(s)

Funder type
Industry

Funder Name
Phase Pharmaceuticals LLC

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 will be posted on or after the date of publication of full trial details.

Intention to publish date
10/05/2028

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