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

Submission date 04/08/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] 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.

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Additional identifiers

Integrated Research Application System (IRAS)
1012438

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Other, Safety, Efficacy

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

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Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
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Key secondary outcome(s)
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Completion date
03/11/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

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
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Sponsor information

Organisation
Phase Pharmaceuticals LLC

Funder(s)

Funder type
Industry

Funder Name

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