

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

<b>Submission date</b> 04/08/2025	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/08/2025	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/08/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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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### Type(s)

Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

1012438

### ClinicalTrials.gov (NCT)

Nil known

### 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

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### 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

### 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

Merthyr Tydfil Industrial Park

Pentrebach

Merthyr Tydfil

Mid Glamorgan

United Kingdom

CF48 4DR

**Sponsor information****Organisation**

Phase Pharmaceuticals LLC

**Funder(s)**

**Funder type**

Industry

**Funder Name**

Phase Pharmaceuticals LLC

## **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