

# Phase I trial HMR code: 25-004

<b>Submission date</b> 15/08/2025	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/09/2025	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/11/2025	<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 sponsor has confirmed that the trial meets the criteria for 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)

Principal investigator

### Contact name

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Public

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

1012103

### **Protocol serial number**

IRAS 1012103; HMR code: 25-004

## **Study information**

### **Scientific Title**

Phase I trial HMR code: 25-004 [The full scientific title will be published within 30 months after the end of the trial]

### **Study objectives**

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### **Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 05/08/2025, London – Brent Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 71048128; brent.rec@hra.nhs.uk), ref: 25/LO/0420

**Study design**

Phase I pharmacokinetics trial in up to 68 healthy postmenopausal participants

**Primary study design**

Interventional

**Study type(s)**

Other

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

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)**

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**Key secondary outcome(s)**

The sponsor has confirmed that the trial meets the criteria for 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.

**Completion date**

30/07/2026

**Eligibility**

**Key inclusion criteria**

Healthy human volunteer

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

Female

**Total final enrolment**

0

**Key exclusion criteria**

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**Date of first enrolment**

03/09/2025

**Date of final enrolment**

30/04/2026

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Hammersmith Medicines Research (HMR)**

Cumberland Avenue, Park Royal

London

England

NW10 7EW

## Sponsor information

**Organisation**

Besins Healthcare Ireland Ltd

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
Besins Healthcare Ireland Ltd

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not expected to be made available