ISRCTN60121726 https://doi.org/10.1186/ISRCTN60121726

Phase I trial HMR code: 25-004

Submission date 15/08/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 02/09/2025	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 17/07/2026	**Condition category** Other	[_] Individual participant data [X] 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.

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Additional identifiers

Integrated Research Application System (IRAS)
1012103

Protocol serial number
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

Primary study design
Interventional

Study design
Phase I pharmacokinetics trial in up to 68 healthy postmenopausal participants

Study type(s)
Other

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
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.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(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.

Primary 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.

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
15/04/2026

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)

Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

Total final enrolment
52

Key exclusion criteria
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.

Date of first enrolment
03/09/2025

Date of final enrolment
15/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Medicines Research (HMR)
Cumberland Avenue, Park Royal
London
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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