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

Phase I trial HMR code: 25-004

Submission date 15/08/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 02/09/2025	**Overall study status** Deferred	
Last Edited 02/09/2025	**Condition category** Other	

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
Dr Takahiro Yamamoto

Contact details
Hammersmith Medicines Research
Cumberland Avenue
Park Royal
London
United Kingdom
NW10 7EW
+44 (0)20 8961 4130
rec@hmrlondon.com

Type(s)
Scientific

Contact name
Dr Clinical Operations Department

Contact details
Besins Healthcare Ireland Ltd.
Level 4, Plaza 4
Custom House Plaza
International Financial Services Centre

Harbourmaster Place
Dublin 1
Dublin
Ireland
D01 A9N3
+353 871039215
clinicaloperations@besins-healthcare.com

Type(s)
Public

Contact name
Dr Clinical Operations Department

Contact details
Besins Healthcare Ireland Ltd
Level 4, Plaza 4
Custom House Plaza
International Financial Services Centre
Harbourmaster Place
Dublin 1
Dublin
Ireland
D01 A9N3
+353 871039215
clinicaloperations@besins-healthcare.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1012103

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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.

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

Secondary study design
Randomized, open-label, crossover trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format

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

Pharmaceutical study type(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.

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 measure
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.

Secondary outcome measures
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.

Overall study start date
23/06/2025

Completion date
30/07/2026

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Female

Target number of participants
Up to 68

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
30/04/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hammersmith Medicines Research (HMR)
Cumberland Avenue, Park Royal
London
United Kingdom
NW10 7EW

Sponsor information

Organisation
Besins Healthcare Ireland Ltd

Sponsor details
Level 4, Plaza 4
Custom House Plaza
International Financial Services Centre
Harbourmaster Place
Dublin 1
Dublin
Ireland
D01 A9N3
+353 871039215
clinicaloperations@besins-healthcare.com

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Besins Healthcare Ireland Ltd

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

Intention to publish date
30/10/2028

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