ISRCTN23370352 https://doi.org/10.1186/ISRCTN23370352

Phase I trial: CA47303

Submission date 08/04/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/04/2025	**Overall study status** Deferred	
Last Edited 10/04/2025	**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.

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1011728

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CA47303

Study information

Scientific Title
Phase I trial: CA47303

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 02/04/2025, East of England - Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 207 104 8096; cambridgeeast.rec@hra.nhs.uk), ref: IRAS ID 1011728

2. Approved 02/04/2025, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 2030806000; info@mhra.gov.uk), ref: IRAS ID 1011728

Study design
Relative Bioavailability study in 20 healthy adult female volunteers

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
No participant information sheet available

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

Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Relative Bioavailability

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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.

Secondary outcome measures
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Overall study start date
04/05/2025

Completion date
14/05/2025

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
20

Key exclusion criteria
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Date of first enrolment
16/04/2025

Date of final enrolment
18/04/2025

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Celerion GB Ltd
22-24 Lisburn Road
Belfast
United Kingdom
BT9 6AD

Sponsor information

Organisation
Millicent Puerto Rico LLC

Sponsor details
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Millicent Puerto Rico LLC

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

Intention to publish date
14/11/2027

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