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 [_] 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

Integrated Research Application System (IRAS)
1011728

Protocol serial number
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

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))
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Completion date
14/05/2025

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

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

United Kingdom

Northern Ireland

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

Sponsor information

Organisation
Millicent Puerto Rico LLC

Funder(s)

Funder type
Industry

Funder Name
Millicent Puerto Rico 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