

# Phase I trial: CA47303

<b>Submission date</b> 08/04/2025	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/04/2025	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/04/2025	<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 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

### Contact name

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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

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.

## 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

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.

**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**

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**Secondary outcome measures**

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.

**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**

100 Alhambra Granada Boulevard, Caguas

Puerto Rico

United States of America

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+1-862-701-5097

herman.ellman@millicentpharma.com

**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