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Phase 1 trial: CA38951

Submission date 09/02/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 14/02/2024	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 14/02/2024	**Condition category** Other	[ ] Individual participant data [ ] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1006327

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1006327, CA38951

Study information

Scientific Title
Phase 1 trial: CA38951

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 10/11/2022, London - West London & GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 207 1048 007; westlondon.rec@hra.nhs.uk), ref: 22/LO/0682

2. Approved 10/11/2022, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 20 3080 6000;; info@mhra.gov.uk), ref: CTA 55384/0004/001-0001

Study design
Phase 1 bioavailability study in 36 healthy 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
Other

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
08/09/2022

Completion date
10/03/2023

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
36

Key exclusion criteria
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Date of first enrolment

21/11/2022

Date of final enrolment
11/12/2022

Locations

Countries of recruitment
Northern Ireland

United Kingdom

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

Sponsor information

Organisation
Millicent Pharma Limited

Sponsor details
Block 4, Floor 2
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Publication and dissemination plan
Full trial details may 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
10/09/2025

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