

Phase 1 trial: CA38951

Submission date 09/02/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/02/2024	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/02/2024	Condition category Other	<input type="checkbox"/> Individual participant data
		<input 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

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1006327

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 1006327, CA38951

Study information

Scientific Title

Phase 1 trial: CA38951

Study objectives

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Ethics approval required

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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

Study type(s)

Other

Health condition(s) or problem(s) studied

Healthy volunteers

Interventions

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Intervention Type

Other

Primary outcome(s)

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Key secondary outcome(s)

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.

Completion date

10/03/2023

Eligibility

Key inclusion criteria

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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

21/11/2022

Date of final enrolment

11/12/2022

Locations

Countries of recruitment

United Kingdom

Northern Ireland

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

Sponsor information

Organisation
Millicent Pharma Limited

Funder(s)

Funder type
Industry

Funder Name
Millicent Pharma Limited

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