ISRCTN46343886 https://doi.org/10.1186/ISRCTN46343886

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

Contact name
Dr Nadine Abdullah

ORCID ID
https://orcid.org/0000-0001-7772-7724

Contact details
22-24 Lisburn Road
Belfast
United Kingdom
BT9 6AD
+44 2890 554040
nadine.abdullah@celerion.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1006327

Protocol serial number
IRAS 1006327, CA38951

Study information

Scientific Title
Phase 1 trial: CA38951

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 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
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(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.

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
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.

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
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.

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