

Phase I trial, Quotient Code: QSC300720

Submission date 14/07/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/07/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/07/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

The sponsor has confirmed that the trial meets the criteria for 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

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1007785

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 1007785

Study information

Scientific Title

Phase I trial, Quotient Code: QSC300720 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives

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Ethics approval required

Ethics approval required

Ethics approval(s)

1. Submitted 06/07/2023, London Surrey Borders REC (2nd Floor 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8057; Surreyborders.rec@hra.nhs.uk), ref: 23/LO/0521

2. Submitted 06/07/2023, MHRA (10 South Colonnade, Canary Wharf, London , E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 58311/0001/001-0001

Study design

One-part single-centre non-randomized open-label study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Pharmaceutical testing facility

Study type(s)

Other

Participant information sheet

Not available in web format

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Drug

Pharmaceutical study type(s)

Pharmacokinetic

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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Overall study start date

06/07/2023

Completion date

16/02/2024

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

16

Key exclusion criteria

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Date of first enrolment

27/09/2023

Date of final enrolment

16/02/2024

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Quotient Sciences Limited

Mere Way

Ruddington Fields

Ruddington

Nottingham

United Kingdom

NG11 6JS

Sponsor information

Organisation

Veradermics Inc

Sponsor details

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Sponsor type

Industry

Website

<https://www.veradermics.com/>

Funder(s)

Funder type

Industry

Funder Name

Veradermics Inc

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

16/08/2026

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