

Phase 1 Trial: Quotient Code QSC303303, Sponsor Code LMNL6511C1002

Submission date 22/04/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/05/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/05/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" 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. Full details will be added to the study record within 30 months after the trial has ended.

Contact information

Type(s)

Public, Scientific

Contact name

Dr Clinical Trial Information

Contact details

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Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1011852

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Quotient Code QSC303303, Sponsor Code LMNL6511C1002

Study information

Scientific Title

Phase 1 Trial: Quotient Code QSC303303, Sponsor Code LMNL6511C1002

Study objectives

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Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 14/05/2025, London - Surrey Borders Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)20 7104 8057; surreyboundaries.rec@hra.nhs.uk), ref: 25/LO/0200

Study design

Two part single centre randomized double-blind study to assess biomarkers safety tolerability and pharmacokinetics

Primary study design

Interventional

Secondary study design

Randomised controlled trial

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, Pharmacodynamic

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. Full details will be added to the study record within 30 months after the trial has ended.

Overall study start date

01/04/2025

Completion date

04/05/2026

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

66 (maximum of 72)

Key exclusion criteria

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Date of first enrolment

02/06/2025

Date of final enrolment

04/05/2026

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

Liminal BioSciences Limited

Sponsor details

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Sponsor type

Industry

Website

<https://liminalbiosciences.com/>

Funder(s)**Funder type**

Industry

Funder Name

Liminal BioSciences Limited

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 of the 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 trial details.

Intention to publish date

04/11/2028

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