

Phase I trial, Quotient code: QSC301137, Sponsor code: LMNL6511C1001

Submission date 26/10/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/11/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/01/2025	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

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1008478

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 1008478; Quotient code: QSC301137, Sponsor code: LMNL6511C1001

Study information

Scientific Title

Phase I trial, Quotient code: QSC301137 [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

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Ethics approval(s)

1. approved 01/12/2023, South Central – Berkshire Research Ethics Committee (Bristol HRA Centre, Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8178; berkshire.rec@hra.nhs.uk), ref: 23/SC/0264

2. approved 01/12/2023, MHRA (10 South Colonnade, Canary Wharf, London , E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 46871/0003/001-0001

Study design

Two-part single-centre randomized study to assess pharmacokinetics, safety and tolerability in 88 healthy volunteers

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

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Key secondary outcome(s)

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.

Completion date

23/07/2024

Eligibility**Key inclusion criteria**

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

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Date of first enrolment

06/12/2023

Date of final enrolment

23/07/2024

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**Quotient Sciences Limited**

Mere Way

Ruddington Fields

Ruddington

Nottingham

United Kingdom

NG11 6JS

Sponsor information**Organisation**

Liminal BioSciences (United Kingdom)

ROR

<https://ror.org/00vwx9s89>

Funder(s)

Funder type

Industry

Funder Name

Liminal BioSciences Ltd

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes