ISRCTN46791858 https://doi.org/10.1186/ISRCTN46791858

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

Submission date 26/10/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 01/11/2023	**Overall study status** Deferred	
Last Edited 08/01/2025	**Condition category** Other	

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
1008478

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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
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.

Ethics approval required
Ethics approval required

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

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
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.

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date

02/10/2023

Completion date
23/07/2024

Eligibility

Key inclusion criteria
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.

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
88

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
England

United Kingdom

Study participating centre
Quotient Sciences Limited
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Sponsor information

Organisation
Liminal BioSciences (United Kingdom)

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Sponsor type
Industry

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ROR
https://ror.org/00vvx9s89

Funder(s)

Funder type
Industry

Funder Name
Liminal BioSciences Ltd

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 highly 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 full trial details.

Intention to publish date
24/01/2027

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