

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

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

Dr Nand Singh

### Contact details

Quotient Sciences Limited  
Mere Way  
Ruddington Fields  
Ruddington  
Nottingham  
United Kingdom  
NG11 6JS  
+44 (0)330 303 1000  
Recruitment@weneedyou.co.uk

### Type(s)

Public, Scientific

### Contact name

Ms Catherine Simcock

### Contact details

Liminal BioSciences Ltd.  
Unit 1, Iconix Park  
London Road  
Sawston  
Cambridge  
United Kingdom  
CB22 3EG  
-  
info@liminalbiosciences.com

## 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**

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.

**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)**

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.

**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**

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.

**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**

Mere Way

Ruddington Fields

Ruddington

Nottingham

United Kingdom  
NG11 6JS

## Sponsor information

### Organisation

Liminal BioSciences (United Kingdom)

### Sponsor details

Unit 1, Iconix Park  
London Road  
Sawston  
Cambridge  
England  
United Kingdom  
CB22 3EG

-

info@liminalbiosciences.com

### Sponsor type

Industry

### Website

<https://liminalbiosciences.com/>

### ROR

<https://ror.org/00v vx9s89>

## 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