

Phase I Trial: Quotient Code QSC301789

Submission date 24/10/2025	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 24/10/2025	Overall study status Deferred	☐ Statistical analysis plan ☐ Results
Last Edited 24/10/2025	Condition category Other	☐ Individual participant data ☒ 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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Type(s)

Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
1012766

Protocol serial number
Sponsor Code LRK-4189-101

Study information

Scientific Title

Phase I Trial: Quotient Code QSC301789 [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)

Submitted 26/08/2025, Wales REC 2 (Castlebridge 5, Cardiff, CF11 9AB, United Kingdom; +44 (0) 2920 785738; wales.REC2@wales.nhs.uk), ref: 25/WA/0222

Primary study design
Interventional

Study design

First-in-man single ascending dose single-centre randomized study to assess the pharmacokinetics safety and tolerability in 48 healthy volunteers

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

24/04/2026

Eligibility**Key inclusion criteria**

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

All

Key exclusion criteria

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Date of first enrolment

27/10/2025

Date of final enrolment

24/04/2026

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**

Larkspur Biosciences

Funder(s)**Funder type**

Industry

Funder Name

Larkspur Biosciences

Results and Publications

Individual participant data (IPD) sharing plan

Not expected to be made available.

IPD sharing plan summary

Not expected to be made available