ISRCTN11217072 https://doi.org/10.1186/ISRCTN11217072

Phase I Trial: Quotient Code QSC301789

Submission date 24/10/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/10/2025	**Overall study status** Deferred	
Last Edited 24/10/2025	**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

Type(s)
Principal investigator

Contact name
Dr Sharan Sidhu

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
Dr Clinical Trials Information

Contact details
One Canal Park
Suite 210
Cambridge, Massachusetts

United States of America
MA 02141
+1-617-693-1232
trialinfo@larkspur.bio

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
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)
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
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

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(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.

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
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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

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
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