ISRCTN80239074 https://doi.org/10.1186/ISRCTN80239074

Phase I Trial: Quotient Code QSC302246

Submission date 05/11/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/11/2025	**Overall study status** Deferred	
Last Edited 15/12/2025	**Condition category** Not Specified	

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. Full details will be added to the study record within 30 months after the trial has ended.

Contact information

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Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1012925

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Quotient code QSC302246

Study information

Scientific Title
Phase I Study: Quotient Code QSC302246 [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)
approved 10/11/2025, London – Surrey Borders Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)20 7972 8143; surreyborders.rec@hra.nhs.uk), ref: 25/LO/0653

Study design
Bioavailability and pharmacokinetic study in healthy volunteers.

Primary study design
Interventional

Study type(s)
Other

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

Phase
Phase I

Drug/device/biological/vaccine name(s)
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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
06/01/2026

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Adult

Sex
Male

Total final enrolment

0

Key exclusion criteria
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Date of first enrolment
28/11/2025

Date of final enrolment
20/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way
Ruddington Fields
Ruddington
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England
NG11 6JS

Sponsor information

Organisation
Galen Limited

Funder(s)

Funder type
Not defined

Funder Name
Galen Limited

Results and Publications

Individual participant data (IPD) sharing plan

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