ISRCTN47999700 https://doi.org/10.1186/ISRCTN47999700

Phase I Study: Quotient Code QSC303166

Submission date 01/09/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 02/09/2025	**Overall study status** Deferred	
Last Edited 02/09/2025	**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. Full details will be added to the study record within 30 months after the trial has ended.

Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1012021

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Quotient code QSC303166

Study information

Scientific Title
Phase I Study: Quotient Code QSC303166 [the full scientific title will be published within 30 months after the end of the trial]

Acronym
Not applicable

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 01/07/2025, Wales Research Ethics Committee 2 (Health and Care Research Wales, Castlebridge 5, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2920 230 457; Wales.REC2@wales.nhs.uk), ref: 25/WA/0163

Study design
Pharmacokinetic and food effect study in healthy volunteers

Primary study design
Interventional

Secondary study design
Partially randomised study

Study setting(s)
Pharmaceutical testing facility

Study type(s)

Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Overall study start date
01/07/2025

Completion date
30/03/2026

Eligibility

Key inclusion criteria

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Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
64

Key exclusion criteria
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.

Date of first enrolment
05/09/2025

Date of final enrolment
30/03/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Quotient Sciences Limited
Mere Way, Ruddington Fields, Ruddington
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Sponsor information

Organisation

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharmaceuticals UK Limited

Alternative Name(s)
Novartis UK, NOVARTIS UK LIMITED

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

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 of the trial details is deferred because of the high 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 trial details.

Intention to publish date
30/09/2028

Individual participant data (IPD) sharing plan
Not expected to be made available

IPD sharing plan summary
Not expected to be made available