

Phase I Study: Quotient Code QSC303166

Submission date 01/09/2025	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/09/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/09/2025	Condition category 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. 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

Contact name

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Additional identifiers

Integrated Research Application System (IRAS)

1012021

Protocol serial number

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

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

Completion date

30/03/2026

Eligibility**Key inclusion criteria**

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

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Date of first enrolment

05/09/2025

Date of final enrolment

30/03/2026

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**

Novartis Pharmaceuticals UK Limited

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

Individual participant data (IPD) sharing plan

Not expected to be made available

IPD sharing plan summary

Not expected to be made available