# Phase I Study: Quotient Code QSC303166

Submission date	Recruitment status	[X] Prospectively registered
01/09/2025	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
02/09/2025	Deferred	Results
Last Edited	Condition category	Individual participant data
02/09/2025	Other	[X] 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

Dr Litza McKenzie

#### Contact details

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## Type(s)

Public, Scientific

#### Contact name

Dr. Novartis Study Director

#### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

1012021

### ClinicalTrials.gov (NCT)

Nil known

#### 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)

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.

### 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

#### **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes