# Phase I trial: Quotient Code QSC207871

Submission date	Recruitment status	[X] Prospectively registered
09/08/2024	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
12/08/2024	Deferred	Results
Last Edited	Condition category	Individual participant data
12/08/2024	Other	<ul><li>Record updated in last year</li></ul>

### 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 Stuart Mair

#### Contact details

Quotient Sciences Ltd,
Mere Way, Ruddington Fields
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United Kingdom
NG11 6JS
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## Type(s)

Public, Scientific

#### Contact name

Mr Sachin Desai

#### Contact details

Novartis Pharma AG, Lichtstrasse 35 Basel Switzerland

# Additional identifiers

## Integrated Research Application System (IRAS)

1009805

### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

IRAS ID 1009805, QSC207871

# Study information

#### Scientific Title

Phase I trial: Quotient code QSC207871 [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 26/07/2024, Wales Research Ethics Committee 2 (Health and Care Research Wales, Castlebridge 5, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 02922941119; Wales.REC2@wales.nhs.uk), ref: 24/WA/0158

# Study design

First-in-man safety tolerability and pharmacokinetic study in approximately 43 healthy participants

# Primary study design

Interventional

## Study type(s)

Safety

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

## Completion date

03/02/2025

# **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 13/08/2024

Date of final enrolment 03/02/2025

# 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 Pharma AG

# Funder(s)

Funder type Industry

**Funder Name**Novartis Pharma AG

# **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results or non-therapeutical clinical trials.

## 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 11/11/2025 No Yes