

Phase I trial: Quotient Code QSC207871

Submission date 09/08/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/08/2024	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/03/2026	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. 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

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Type(s)

Public, Scientific

Contact name

None Novartis Study Director

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Additional identifiers

Integrated Research Application System (IRAS)
1009805

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

Total final enrolment

0

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

England

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**IPD sharing plan summary**

Not expected to be made available