ISRCTN12178605 https://doi.org/10.1186/ISRCTN12178605

# Phase I trial: Quotient Code QSC207871

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| **Submission date**<br>09/08/2024 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>12/08/2024 | **Overall study status**<br>Deferred | |
| **Last Edited**<br>12/08/2024 | **Condition category**<br>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. The full details will be added to the study record within 30 months after the trial has ended.

## Contact information

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number
1009805

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
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
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.

### 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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Pharmaceutical testing facility

### Study type(s)

Safety

### Participant information sheet
Not available in web format

### Health condition(s) or problem(s) studied
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.

### Interventions
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.

### Intervention Type
Drug

### Pharmaceutical study type(s)
Pharmacokinetic, Pharmacogenetic

### Phase
Phase I

### Drug/device/biological/vaccine name(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.

### Primary outcome measure
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.

### Secondary outcome measures
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.

### Overall study start date
05/06/2024

### Completion date
03/02/2025

## Eligibility

### Key inclusion criteria

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.

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Sex
Both

### Target number of participants
43

### Key exclusion criteria
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.

### Date of first enrolment
13/08/2024

### Date of final enrolment
03/02/2025

## 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

Novartis Pharma AG

### Sponsor details
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### Sponsor type
Industry

## Funder(s)

### Funder type
Industry

### Funder Name
Novartis Pharma AG

## 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 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 will be posted on or after the date of publication of full trial details.

### Intention to publish date
02/08/2027

### 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