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

Phase I trial: Quotient Code QSC207871

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

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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

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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