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

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

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

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. The 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. 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