ISRCTN65070683 https://doi.org/10.1186/ISRCTN65070683

Phase I trial: Quotient code QSC301152

Submission date 14/12/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 18/12/2023	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 18/12/2023	**Condition category** Other	[_] Individual participant data [_] 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

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Additional identifiers

Integrated Research Application System (IRAS)
1008350

Protocol serial number
QSC301152

Study information

Scientific Title
Phase I trial: Quotient code QSC301152 [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 06/12/2023, London Chelsea REC (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8150; chelsea.rec@hra.nhs.uk), ref: 23/LO/0799

Primary study design
Interventional

Study design
First-in-man safety pharmacokinetics and pharmacodynamics trial

Study type(s)
Safety

Health condition(s) or problem(s) studied
Healthy volunteers

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
07/04/2025

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
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Date of first enrolment
18/12/2023

Date of final enrolment
07/04/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way, Ruddington
Nottingham
United Kingdom
NG11 6JS

Sponsor information

Organisation
Novartis (Switzerland)

ROR
https://ror.org/02f9zrr09

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharma

Alternative Name(s)
Novartis Deutschland GmbH, Novartis Pharma GmbH, Novartis Deutschland

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

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 of non-therapeutic clinical trials.

IPD sharing plan summary
Not expected to be made available