ISRCTN16482972 https://doi.org/10.1186/ISRCTN16482972

Phase I Trial: Quotient Code QSC205832

Submission date 22/03/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/03/2023	**Overall study status** Deferred	
Last Edited 23/03/2023	**Condition category** Other	

Plain English summary of protocol
The Health Research Authority (HRA) has approved 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
2022-02525-10

IRAS number
1006182

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1006182, Quotient Code: QSC205832

Study information

Scientific Title
Phase I Trial: QSC205832 [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
Old ethics approval format

Ethics approval(s)
1. Approved 03/03/2023, HSC REC A (Office for Research Ethics Committees in Northern Ireland (ORECNI), Business Services Organisation, Lissue Industrial Estate West, Rathdown Walk, Moira

Road, Lisburn, Co. Antrim BT28 2RF, UK; +44 (0)28 95 361400; reca@hscni.net), ref: 22/NI/0169 2. Approved 03/03/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 04935/0231/001-0001

Study design
Phase I trial to assess safety and pharmacokinetics in 16 healthy volunteers

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format

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)
The Health Research Authority (HRA) has approved 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 Health Research Authority (HRA) has approved 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 Health Research Authority (HRA) has approved 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
15/11/2022

Completion date
19/11/2023

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
16

Key exclusion criteria
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Date of first enrolment
28/03/2023

Date of final enrolment
19/11/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Quotient Sciences
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Sponsor type
Industry

Website
https://www.novartis.com/

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

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
30/01/2026

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