ISRCTN10521680 https://doi.org/10.1186/ISRCTN10521680

Phase I trial, Quotient code: QSC205601

Submission date 31/01/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/02/2022	**Overall study status** Deferred	
Last Edited 01/02/2022	**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 when the results are published, which will be within 30 months after the trial has ended.

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Additional identifiers

Clinical Trials Information System (CTIS)
2021-000600-38

Integrated Research Application System (IRAS)
304054

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 304054; Quotient code: QSC205601

Study information

Scientific Title
Phase I trial, Quotient code: QSC205601 [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 24/11/2021, London Bridge Research Ethics Committee (London HRA Centre, 2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 1048202, +44 (0)207 1048124; londonbridge.rec@hra.nhs.uk), REC ref: 21/LO/0761
2. Approved 31/12/2021, MHRA (10 South Colonnade, Canary Wharf, London E14 4PU, UK; +44 (0)20 3080 6000; info@nhra.gov.uk), ref: CTA 04935/0192/001-0001
The HRA has approved deferral of publication of trial details.

Study design
Phase I trial to assess safety, tolerability and pharmacokinetics in 116 healthy volunteers

Primary study design
Other

Study type(s)
Other

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)
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Primary outcome(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 when the results are published, which will be within 30 months after the trial has ended.

Key secondary outcome(s))
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Completion date

06/10/2022

Eligibility

Key inclusion criteria
Healthy human volunteer

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
02/02/2022

Date of final enrolment
06/10/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences
Trent House
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Sponsor information

Organisation
Novartis (Switzerland)

ROR
https://ror.org/02f9zrr09

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharma AG

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes