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

EudraCT/CTIS number
2021-000600-38

IRAS number
304054

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

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

Secondary outcome measures
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Overall study start date
13/10/2021

Completion date
06/10/2022

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
116

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
England

United Kingdom

Study participating centre
Quotient Sciences
Trent House
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Ruddington Fields Business Park
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Sponsor information

Organisation
Novartis (Switzerland)

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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 AG

Results and Publications

Publication and dissemination plan
Trial information and summary results 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 1 information.

Intention to publish date
06/04/2025

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