

Phase I trial, Quotient code: QSC205601

Submission date 31/01/2022	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 01/02/2022	Overall study status Deferred	☐ Statistical analysis plan ☐ Results
Last Edited 18/02/2026	Condition category Other	☐ Individual participant data ☒ Record updated in last year

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.

Contact information

Type(s)

Principal investigator

Contact name

Dr Stuart Mair

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Type(s)

Scientific, Public

Contact name

None - Novartis Study Director

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Additional identifiers

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

Integrated Research Application System (IRAS)
304054

Protocol serial number
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.

Primary study design

Other

Study design

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

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)

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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

Total final enrolment

101

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

Mere Way

Ruddington Fields Business Park

Nottingham

England

NG11 6JS

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

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