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

# Phase I trial, Quotient code: QSC205601

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|---|---|---|
| **Submission date**<br>31/01/2022 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>01/02/2022 | **Overall study status**<br>Deferred | |
| **Last Edited**<br>01/02/2022 | **Condition category**<br>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.

## Contact information

**Type(s)**
Public

**Contact name**
Dr Stuart Mair

**Contact details**
Quotient Sciences Limited
Mere Way
Ruddington Fields
Ruddington
Nottingham
United Kingdom
NG11 6JS
+44 (0)3303031000
recruitment@weneedyou.co.uk

**Type(s)**
Scientific

**Contact name**
Dr Stuart Mair

**Contact details**
Quotient Sciences Limited
Mere Way
Ruddington Fields

Ruddington
Nottingham
United Kingdom
NG11 6JS
+44 (0)3303031000
recruitment@weneedyou.co.uk

### Type(s)
Principal Investigator

### Contact name
Dr Stuart Mair

### Contact details
Quotient Sciences Limited
Mere Way
Ruddington Fields
Ruddington
Nottingham
United Kingdom
NG11 6JS
+44 (0)1159749000
recruitment@weneedyou.co.uk

## 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
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.

## 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 when the results are published, which will be 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 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
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.

### 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
Mere Way
Ruddington Fields Business Park
Nottingham
United Kingdom
NG11 6JS

# Sponsor information

**Organisation**
Novartis (Switzerland)

**Sponsor details**
Lichtstr. 35
Basel
Switzerland
4056
-
novartis.email@novartis.com

**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 |