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

# Phase I Trial: Quotient Code QSC205832

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|---|---|---|
| **Submission date**<br>22/03/2023 | **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>23/03/2023 | **Overall study status**<br>Deferred | |
| **Last Edited**<br>23/03/2023 | **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 within 30 months after the trial has ended.

## Contact information

**Type(s)**
Principal investigator

**Contact name**
Dr Litza McKenzie

**Contact details**
Mere Way
Ruddington Fields
Ruddington
Nottingham
United Kingdom
NG11 6JS
+44 (0)330 3031000
recruitment@weneedyou.co.uk

**Type(s)**
Public

**Contact name**
Ms Cecile Hauschka

**Contact details**
Lichtstrasse 35
Basel
Switzerland
4056

+41 (0)79 704 14 71
cecile.hauschka@novartis.com

### Type(s)
Public

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Ms Cecile Hauschka

### Contact details
Lichtstrasse 35
Basel
Switzerland
4056
+41 (0)79 704 14 71
cecile.hauschka@novartis.com

## Additional identifiers

### Clinical Trials Information System (CTIS)
2022-02525-10

### Integrated Research Application System (IRAS)
1006182

### Protocol serial number
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

### Study type(s)
Other

### 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 within 30 months after the trial has ended.

### 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 within 30 months after the trial has ended.

### Key secondary 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 within 30 months after the trial has ended.

### Completion date
19/11/2023

## Eligibility

### Key inclusion criteria
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### 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
28/03/2023

### Date of final enrolment
19/11/2023

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Quotient Sciences**
Mere Way
Ruddington Fields
Ruddington
Nottingham
United Kingdom
NG11 6JS

## Sponsor information

### Organisation
Novartis (Switzerland)

### 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

**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