

# Phase I Trial: Quotient Code QSC205832

<b>Submission date</b> 22/03/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/03/2023	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/03/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 within 30 months after the trial has ended.

## Contact information

### Type(s)

Principal Investigator

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## **Additional identifiers**

**EudraCT/CTIS number**  
2022-02525-10

**IRAS number**  
1006182

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
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

## **Secondary study design**

Non randomised study

## **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**

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## **Secondary outcome measures**

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**Overall study start date**

15/11/2022

**Completion date**

19/11/2023

## Eligibility

**Key inclusion criteria**

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**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Sex**

Both

**Target number of participants**

16

**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**

England

United Kingdom

**Study participating centre****Quotient Sciences**

Mere Way  
Ruddington Fields  
Ruddington  
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United Kingdom  
NG11 6JS

## Sponsor information

**Organisation**

Novartis (Switzerland)

**Sponsor details**

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cecile.hauschka@novartis.com

**Sponsor type**

Industry

**Website**

<https://www.novartis.com/>

**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**

**Publication and dissemination plan**

Full trial details 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 I information. Results will be posted on or after the date of publication of full trial details.

**Intention to publish date**

30/01/2026

**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