

Phase I trial, Quotient code: QSC205601

Submission date 31/01/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/02/2022	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/02/2022	Condition category 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 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

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.

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

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.

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

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.

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