

Phase I Study (QSC303441)

Submission date 12/12/2025	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 23/12/2025	Overall study status Deferred	☐ Statistical analysis plan ☐ Results
Last Edited 23/12/2025	Condition category Other	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

The sponsor has confirmed that the trial meets the criteria for 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

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Type(s)

Public, Scientific

Contact name

None Novartis Study Director

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Additional identifiers

Integrated Research Application System (IRAS)
1012643

CRO study code
QSC303441

Study information

Scientific Title
Phase I Study (QSC303441)
The full scientific title will be published within 30 months after the end of the trial.

Study objectives
The sponsor has confirmed that the trial meets the criteria for 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.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/12/2025, HSC REC B (Office for Research Ethics Committees in Northern Ireland (ORECNI), Lissue Industrial Estate West 5 Rathdown Walk, Lisburn, BT28 2RF, United Kingdom; +44 28 9536 1408; RECB@hscni.net), ref: 25-NI-0144

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
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Purpose
Phase 1 study in healthy volunteers

Study type(s)**Health condition(s) or problem(s) studied**

Healthy volunteers

Interventions

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Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

1. . measured using . at .

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Key secondary outcome(s)**Completion date**

12/06/2027

Eligibility**Key inclusion criteria**

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Healthy volunteers allowed

Yes

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

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Date of first enrolment

23/12/2025

Date of final enrolment

12/06/2027

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**Quotient Sciences Limited**

Mere Way, Ruddington Fields, Ruddington

Nottingham

England

NG11 6JS

Sponsor information**Organisation**

Novartis Pharmaceuticals UK Ltd.

Funder(s)**Funder type**

Funder Name

Novartis Pharmaceuticals UK Limited

Alternative Name(s)

Novartis UK, NOVARTIS UK LIMITED

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available