ISRCTN75963665 https://doi.org/10.1186/ISRCTN75963665

Phase I Study (QSC303441)

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

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
Dr Litza McKenzie

Contact details
Mere Way, Ruddington Fields
Ruddington
Nottingham
United Kingdom
NG11 6JS
+44 1159749000
recruitment@weneedyou.co.uk

Type(s)
Public, Scientific

Contact name
None Novartis Study Director

Contact details
Lichtstrasse 35
Basel
Switzerland

4056
+41 61 324 11 11
novartis.email@novartis.com

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
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.

Purpose
Phase 1 study in healthy volunteers

Study type(s)

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
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.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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.

Primary outcome(s)
1. . measured using . at .

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.

Key secondary outcome(s))

Completion date
12/06/2027

Eligibility

Key inclusion criteria
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.

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
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.

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