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Phase I Trial: Quotient Code QSC301642

Submission date 03/04/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/04/2025	**Overall study status** Deferred	
Last Edited 30/04/2025	**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. Full details will be added to the study record within 30 months after the trial has ended.

Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1011435

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Quotient Code: QSC301642

Study information

Scientific Title
Phase I Trial: Quotient Code QSC301642

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 29/04/2025, London - Surrey Borders Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)20 7104 8057; surreyborders.rec@hra.nhs.uk), ref: 25/LO/0104

Study design
Absorption metabolism distribution and elimination (ADME) study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Pharmaceutical testing facility

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

Pharmaceutical study type(s)
Pharmacokinetic

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
03/03/2025

Completion date
08/06/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
30 Years

Upper age limit
65 Years

Sex
Male

Target number of participants
7

Key exclusion criteria
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Date of first enrolment
05/05/2025

Date of final enrolment
08/06/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Quotient Sciences Limited
Mere Way, Ruddington Fields, Ruddington
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Sponsor information

Organisation
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Sponsor type
Industry

Website
https://www.shionogi.com/eu/en/

Funder(s)

Funder type
Not defined

Funder Name
Shionogi B.V.

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 of the 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 may be posted on or after the date of publication of trial details.

Intention to publish date
08/12/2027

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