ISRCTN11464134 https://doi.org/10.1186/ISRCTN11464134

Phase I Trial: Quotient Code QSC302899

Submission date 26/03/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 28/03/2025	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 30/04/2025	**Condition category** Other	[_] Individual participant data [X] 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. 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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1011191

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Quotient Code: QSC302899

Study information

Scientific Title
Phase I Trial: Quotient Code QSC302899

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/04/2025, 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/0024

Study design
Absorption metabolism distribution and elimination (ADME) study

Primary study design
Interventional

Study type(s)
Other

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(s)
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.

Key secondary outcome(s))
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.

Completion date
08/07/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Upper age limit

65 years

Sex
Male

Key exclusion criteria
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Date of first enrolment
15/04/2025

Date of final enrolment
08/07/2025

Locations

Countries of recruitment
United Kingdom

England

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

Organisation
Shionogi B.V.

Funder(s)

Funder type
Industry

Funder Name
Shionogi B.V.

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes