ISRCTN12857535 https://doi.org/10.1186/ISRCTN12857535

Phase I Trial: Quotient Code QSC301409

Submission date 13/08/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 20/08/2025	**Overall study status** Deferred	
Last Edited 20/08/2025	**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

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Additional identifiers

Integrated Research Application System (IRAS)
1011685

Protocol serial number
QSC301409

Study information

Scientific Title
Phase I Trial: Quotient Code QSC301409

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/08/2025, London - Surrey Borders Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)20 7972 8143; surreyborders.rec@hra.nhs.uk), ref: 25/LO/0338

Primary study design
Interventional

Study design
Absorption metabolism distribution and elimination (ADME) study

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. The 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. The full details will be added to the study record within 30 months after the trial has ended.

Completion date
15/10/2025

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
05/09/2025

Date of final enrolment
15/10/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way
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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