Phase I Trial: Quotient Code QSC302899

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

Type(s)

Public, Scientific

Contact name

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Type(s)

Principal Investigator

Contact name

Dr Nand Singh

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1011191

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

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

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Secondary outcome measures

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.

Overall study start date

11/02/2025

Completion date

08/07/2025

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

15/04/2025

Date of final enrolment

08/07/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Quotient Sciences Limited

Mere Way Ruddington Fields Ruddington Nottingham United Kingdom NG11 6JS

Sponsor information

Organisation

Shionogi B.V.

Sponsor details

Herengracht 464 Amsterdam Netherlands 1017 CA +44 (0)20 3053 4200 regulatory.affairs@shionogi.eu

Sponsor type

Industry

Website

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

Funder(s)

Funder type

Industry

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

08/01/2028

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