

# Phase I Trial: Quotient Code QSC301642

<b>Submission date</b> 03/04/2025	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/04/2025	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/04/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

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### Contact details

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

1011435

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

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; surreyboundaries.rec@hra.nhs.uk), ref: 25/LO/0104

## 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)**

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**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**

08/06/2025

**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**

05/05/2025

**Date of final enrolment**

08/06/2025

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Quotient Sciences Limited**

Mere Way, Ruddington Fields, Ruddington

Nottingham

United Kingdom

NG11 6JS

**Sponsor information****Organisation**

Shionogi B.V.

**Funder(s)****Funder type**

Not defined

**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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes