

Phase I Trial: Quotient Code QSC302899

Submission date 26/03/2025	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/03/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/04/2025	Condition category 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

Ms Cornelia Krueger

Contact details

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

Type(s)

Principal investigator

Contact name

Dr Nand Singh

Contact details

Quotient Sciences Limited
Mere Way
Ruddington Fields
Ruddington
Nottingham

United Kingdom
NG11 6JS
+44 (0)330 303 1000
recruitment@weneedyou.co.uk

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

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.

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; surreyboundaries.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

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.

Interventions

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.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(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.

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

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.

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

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.

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

Ruddington

Nottingham

United Kingdom

NG11 6JS

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