ISRCTN12615820 https://doi.org/10.1186/ISRCTN12615820

Phase I Trial, Quotient Code: QSC207970

Submission date 13/02/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 16/02/2023	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 20/09/2023	**Condition category** Other	[_] Individual participant data [_] 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. 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

EudraCT/CTIS number
2022-002263-30

IRAS number
1007036

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1007036, Quotient Code: QSC207970

Study information

Scientific Title
Phase I Trial, Quotient Code: QSC207970 [The full scientific title will be published within 30 months after the end of the trial]

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
Old ethics approval format

Ethics approval(s)
1. Approved 22/03/2023, London - Surrey Borders (London HRA Centre, 2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ; surreyborders.rec@hra.nhs.uk), ref: 23/LO/0015
2. Approved 22/03/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0)20 3080 6000; info@mhra.gov.uk) ref: CTA 50999/0014/001-0001

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
No participant information sheet available

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
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.

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

Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
31/01/2023

Completion date
08/05/2023

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
6

Key exclusion criteria
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.

Date of first enrolment
03/04/2023

Date of final enrolment
23/04/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Quotient Sciences Limited
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Sponsor information

Organisation
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Sponsor type
Industry

Website
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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 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.

Intention to publish date
08/11/2025

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 nontherapeutic 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?
HRA research summary			20/09/2023	No	No