

Phase I Trial Quotient code: QSC302573

Submission date 11/10/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/10/2024	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/05/2025	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. The full details will be added to the study record within 30 months after the trial has ended.

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1009846

Protocol serial number

IRAS 1009846, QSC302573

Study information

Scientific Title

Phase I Trial Quotient code: QSC302573 [the full scientific title will be published within 30 months after the end of the trial]

Study objectives

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Ethics approval required

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Ethics approval(s)

approved 13/09/2024, Wales Research Ethics Committee 2 (Health and Care Research Wales, Castlebridge 5, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0) 29 2294 1119; Wales.REC2@wales.nhs.uk), ref: 24/WA/0169

Study design

Relative bioavailability and food effect study in 48 healthy volunteers

Primary study design

Interventional

Study type(s)

Safety

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

22/04/2025

Eligibility**Key inclusion criteria**

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

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Date of first enrolment

24/10/2024

Date of final enrolment

23/04/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**Quotient Sciences Limited**

Mere Way, Ruddington Fields, Ruddington

Nottingham

United Kingdom

NG116JS

Sponsor information

Organisation

Otsuka (United States)

ROR

<https://ror.org/00ew4na22>

Funder(s)

Funder type

Industry

Funder Name

Otsuka Pharmaceuticals

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during 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