ISRCTN12823680 https://doi.org/10.1186/ISRCTN12823680

Phase I Trial Quotient code: QSC302573

Submission date 11/10/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 15/10/2024	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 08/05/2025	**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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Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1009846

Protocol serial number
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
Ethics approval required

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

Primary study design
Interventional

Study design
Relative bioavailability and food effect study in 48 healthy volunteers

Study type(s)
Safety

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. The 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. 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)
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Primary 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.

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
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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