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 [X] 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

EudraCT/CTIS number
Nil known

IRAS number
1009846

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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
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 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

Secondary study design
Non randomised study

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Safety

Participant information sheet

Not available in web format.

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

Pharmaceutical study type(s)
Relative Bioavailability, Food Effect

Phase
Phase I

Drug/device/biological/vaccine name(s)
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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
02/07/2024

Completion date
22/04/2025

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

Participant type(s)

Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
48

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
24/10/2024

Date of final enrolment
23/04/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Quotient Sciences Limited
Mere Way, Ruddington Fields, Ruddington
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NG116JS

Sponsor information

Organisation
Otsuka (United States)

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Sponsor type
Industry

Website
https://www.otsuka-us.com/

ROR
https://ror.org/00ew4na22

Funder(s)

Funder type
Industry

Funder Name
Otsuka Pharmaceuticals

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. Results may be posted on or after the date of publication of full trial details.

Intention to publish date
23/10/2027

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