ISRCTN90651766 https://doi.org/10.1186/ISRCTN90651766

Phase I trial: Quotient code QSC301813

Submission date 31/07/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 02/08/2024	**Overall study status** Deferred	
Last Edited 25/09/2024	**Condition category** Other	

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)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1009723

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1009723, Quotient code: QSC301813

Study information

Scientific Title
Phase I trial: Quotient code QSC301813

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, London – Brent Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8117; brent.rec@hra.nhs.uk), ref: 24/LO/0348

Study design
Relative bioavailability study in 14 healthy volunteers

Primary study design
Interventional

Secondary study design

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Other, Safety

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
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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)
Pharmacokinetic, Relative bioavailability

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
15/07/2024

Completion date
29/01/2025

Eligibility

Key inclusion criteria
Healthy volunteer

Participant type(s)

Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
14

Key exclusion criteria
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Date of first enrolment
16/09/2024

Date of final enrolment
29/01/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Quotient Sciences Limited
Mere Way
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Sponsor information

Organisation
Carmot Therapeutics (United States)

Sponsor details

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Sponsor type
Industry

Website
https://carmot-therapeutics.us/

ROR
https://ror.org/05ye86j67

Funder(s)

Funder type
Industry

Funder Name
Carmot Therapeutics, Inc.

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
29/07/2027

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