Phase I trial: Quotient code QSC301813

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

Type(s)

Principal Investigator

Contact name

Dr Sharan Sidhu

Contact details

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Type(s)

Public, Scientific

Contact name

Dr Clinical Trials

Contact details

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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

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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

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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

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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

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

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 Ruddington Fields Ruddington Nottingham United Kingdom NG11 6JS

Sponsor information

Organisation

Carmot Therapeutics (United States)

Sponsor details

740 Heinz Avenue
Berkeley
United States of America
CA 94710
+1 (888) 402-4674
global.trial_information@roche.com

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