ISRCTN85847953 https://doi.org/10.1186/ISRCTN85847953

Phase I trial, Quotient Code: QSC300414

Submission date 05/05/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/05/2023	**Overall study status** Deferred	
Last Edited 09/05/2023	**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.

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1007622

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 1007622, Quotient Code: QSC300414

Study information

Scientific Title
Phase I trial, Quotient Code: QSC300414 [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
Old ethics approval format

Ethics approval(s)

1. Submitted 18/04/2023, HSC REC B (ORECNI, Business Services Organisation, Lissue Industrial Estate West, Lisburn, Co. Antrim BT28 2RF, Northern Ireland, UK; +44 (0)28 9536 1400; recb@hscni.net), ref: 23/NI/0043
2. Submitted 18/04/2023, MHRA (10 South Colonnade, Canary Wharf, London E14 4PU, UK; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 57954/0001/001-0001

Study design
Two-part single-center double-blind randomiZed study to assess PK, safety and tolerability in 104 healthy volunteers

Primary study design
Interventional

Study type(s)
Other

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)
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
24/03/2024

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
27/06/2023

Date of final enrolment
14/03/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
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Sponsor information

Organisation
D. E. Shaw Research

ROR
https://ror.org/02s04h872

Funder(s)

Funder type
Industry

Funder Name
D. E. Shaw Research

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes