

Phase I trial, Quotient Code: QSC300414

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| Submission date 05/05/2023 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 09/05/2023 | Overall study status Deferred | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 09/05/2023 | Condition category Other | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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)

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Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1007622

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)

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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

Mere Way

Ruddington Fields

Ruddington

Nottingham

United Kingdom

NG11 6JS

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