

# Phase I trial, Quotient Code: QSC300414

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

Principal investigator

### Contact name

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### Type(s)

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### **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

### **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**

Mere Way

Ruddington Fields

Ruddington

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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