

Phase I trial, Quotient Code: QSC300414

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)

Principal Investigator

Contact name

Dr Nand Singh

Contact details

Quotient Sciences Limited
Mere Way
Ruddington Fields
Ruddington
Nottingham
United Kingdom
NG11 6JS
+44 (0)330 303 1000
Recruitment@weneedyou.co.uk

Type(s)

Scientific

Contact name

Dr Fabrizio Giordanetto

Contact details

120 West 45th Street
39th Floor
New York

United States of America
NY 10036
+1 (0) 212 849 0880
Fabrizio.Giordanetto@DEShawResearch.com

Type(s)

Public

Contact name

Dr Fabrizio Giordanetto

Contact details

120 West 45th Street
39th Floor
New York
United States of America
NY 10036
+1 (0) 212 849 0880
Fabrizio.Giordanetto@DEShawResearch.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1007622

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

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

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

Secondary study design

Randomised parallel trial

Study setting(s)

Pharmaceutical testing facility

Study type(s)

Other

Participant information sheet

Not available in web format

Health condition(s) or problem(s) studied

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.

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

Phase

Phase I

Drug/device/biological/vaccine name(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.

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

18/04/2023

Completion date

24/03/2024

Eligibility

Key inclusion 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.

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

104

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

27/06/2023

Date of final enrolment

14/03/2024

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

D. E. Shaw Research

Sponsor details

120 West 45th Street
39th Floor
New York
United States of America
NY 10036
+1 (0) 212 849 0880
fabrizio.giordanetto@deshawresearch.com

Sponsor type

Industry

Website

<https://www.deshawresearch.com/>

ROR

<https://ror.org/02s04h872>

Funder(s)

Funder type

Industry

Funder Name

D. E. Shaw Research

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 will be posted on or after the date of publication of full trial details.

Intention to publish date

24/09/2026

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