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.

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
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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

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
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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
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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