ISRCTN30858255 https://doi.org/10.1186/ISRCTN30858255

Phase I Trial: Quotient code QSC206231

Submission date 12/11/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 22/11/2024	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 10/12/2024	**Condition category** Other	[_] Individual participant data [X] 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.

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1005504

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1005504, Quotient code: QSC206231

Study information

Scientific Title
Phase I Trial: Quotient code QSC206231

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
Ethics approval required

Ethics approval(s)

Submitted 24/07/2024, HSC REC B (ORECNI, Lissue Industrial Estate West, 5 Rathdown Walk, Lisburn, Co. Antrim, BT28 2RF, United Kingdom; +44 (0)2895361400; recb@hscni.net), ref: 24/NI/0093

Study design
Single-centre randomized study to assess safety, tolerability and pharmacokinetics in 10 healthy volunteers

Primary study design
Interventional

Secondary study design
Randomised controlled 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

Pharmaceutical study type(s)
Pharmacokinetic

Phase
Phase I

Drug/device/biological/vaccine name(s)
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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
24/07/2024

Completion date
07/01/2025

Eligibility

Key inclusion criteria
Healthy volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
10

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
25/11/2024

Date of final enrolment
07/01/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Quotient Sciences Limited
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Nanomerics Ltd

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

Intention to publish date
07/07/2027

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