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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 [_] 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

Integrated Research Application System (IRAS)
1005504

Protocol serial number
Quotient code: QSC206231

Study information

Scientific Title
Phase I Trial: Quotient code QSC206231

Study objectives
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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

Primary study design
Interventional

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

Study type(s)
Other

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)
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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
07/01/2025

Eligibility

Key inclusion criteria
Healthy volunteer

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
25/11/2024

Date of final enrolment
07/01/2025

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
Nanomerics Ltd

Funder(s)

Funder type
Industry

Funder Name
Nanomerics Ltd

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