Phase I Trial: Quotient code QSC206231

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

Contact information

Type(s)

Principal Investigator

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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

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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

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

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Intervention Type

Drug

Pharmaceutical study type(s)

Pharmacokinetic

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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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

Mere Way Ruddington Fields Ruddington Nottingham United Kingdom NG11 6JS

Sponsor information

Organisation

Nanomerics Ltd

Sponsor details

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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