

Phase I Trial: Quotient code QSC206231

Submission date 12/11/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/11/2024	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/12/2024	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.

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1005504

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

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Key secondary outcome(s)

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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

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Nottingham

United Kingdom

NG11 6JS

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