

Phase I Trial: Quotient Code QSC301361

Submission date 08/12/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/12/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/01/2024	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.

Contact information

Type(s)

Principal investigator

Contact name

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Type(s)

Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
1008762

Protocol serial number
Quotient Code: QSC301361

Study information

Scientific Title
Phase I Trial: Quotient Code QSC301361

Study objectives

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Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/01/2024, HSC REC B (ORECNI, Business Services Organisation, Lissue Industrial Estate West, Lisburn, Co. Antrim, BT28 2RF, United Kingdom; +44 2895361400; RECB@hscni.net), ref: 23/NI/0154

Study design
Three-part single-centre double-blind partially-randomized first-in-human study

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

18/12/2024

Eligibility

Key inclusion criteria

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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

08/03/2024

Date of final enrolment

18/12/2024

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**Quotient Sciences Limited**

Mere Way

Ruddington Fields

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Nottingham

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Sponsor information

Organisation

IFM Management, Inc

Funder(s)

Funder type

Industry

Funder Name

IFM Management, Inc

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