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Phase I Trial: Quotient Code QSC301361

Submission date 08/12/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/12/2023	**Overall study status** Deferred	
Last Edited 25/01/2024	**Condition category** Other	

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)
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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil Known

Integrated Research Application System (IRAS)
1008762

ClinicalTrials.gov (NCT)
Nil Known

Protocol serial number
IRAS 1008762, Quotient Code: QSC301361

Study information

Scientific Title
Phase I Trial: Quotient Code QSC301361

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)
approved 05/01/2024, HSC REC B (ORECNI, Business Services Organisation, Lissue Industrial Estate West, Lisburn, Co. Antrium, 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
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
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
Ruddington
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes