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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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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number
1008762

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
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

Secondary study design
Part 1, Part 2 Cohorts 1-4 and 6-7 and Part 3: Randomised Control Trial. Part 2 Cohort 5: Non-randomised Study

Study setting(s)
Pharmaceutical testing facility

Study type(s)

Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
22/11/2023

Completion date
18/12/2024

Eligibility

Key inclusion criteria

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Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
127

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
England

United Kingdom

Study participating centre
Quotient Sciences Limited
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Sponsor information

Organisation
IFM Management, Inc

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
IFM Management, Inc

Results and Publications

Publication and dissemination plan
The full trial details will be published up to 30 months after the end of the trial. Publication of some trial 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
18/06/2027

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