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Deferred registration - Phase I trial - Quotient Sciences code: QSC303633

Submission date 22/05/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 29/05/2026	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 29/05/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date.

Contact information

Type(s)
Principal investigator

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Type(s)
Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
1013723

Study information

Scientific Title
Deferred registration - Phase I trial - Quotient Code: QSC303633 [The full scientific title will be added on or before the deferral expiry date]

Study objectives
This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 10/04/2026, London – Brent Research Ethics Committee (REC) (Health Research Authority 2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 2071048128; brent.rec@hra.nhs.uk), ref: 26/LO/0199

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Dose comparison

Assignment
This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date.

Purpose
Phase I trial in healthy volunteers

Study type(s)

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
1. [Outcome name] measured using [Metric or method of measurement] at [Timepoint(s)]. This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date.

Key secondary outcome(s)

Completion date
05/12/2026

Eligibility

Key inclusion criteria
This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date.

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date.

Date of first enrolment
18/06/2026

Date of final enrolment
05/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way
Ruddington Fields
Ruddington
Nottingham
England
NG11 6JS

Sponsor information

Organisation
Alkermes, Inc

Funder(s)

Funder type

Funder Name
Alkermes, Inc

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available