

Phase I Trial, Quotient Code: QSC300320

Submission date 23/09/2022	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/10/2022	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/02/2024	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

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Additional identifiers

Clinical Trials Information System (CTIS)

2022-002756-39

Integrated Research Application System (IRAS)

1006328

Protocol serial number

Quotient Code: QSC300320

Study information

Scientific Title

Phase I Trial, Quotient Code: QSC300320 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives

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Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 25/10/2022, South Central - Oxford A REC (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8290, (0)207 104 8206, (0)207 104 8061; oxforda.rec@hra.nhs.uk); Ref - 22/SC/0294

2. Approved 25/10/2022, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 00322/0315/001-0001

Study design

Efficacy and safety trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Healthy volunteers

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

10/01/2024

Reason abandoned (if study stopped)

Other reason not related to safety

Eligibility

Key inclusion criteria

Healthy human 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

20/10/2022

Date of final enrolment

26/05/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Quotient Sciences Limited

Mere Way

Ruddington Fields

Ruddington

Nottingham

United Kingdom

NG11 6JS

Sponsor information

Organisation

Norgine (United Kingdom)

ROR

<https://ror.org/046zgtw08>

Funder(s)

Funder type

Industry

Funder Name

Norgine

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 nontherapeutic 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?
HRA research summary			28/06/2023	No	No