

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

Contact name

Dr Litza McKenzie

Contact details

Quotient Sciences Limited
Mere Way
Ruddington Fields
Nottingham
United Kingdom
NG11 6JS
+44 (0)330 303 1000
recruitment@weneedyou.co.uk

Type(s)

Scientific

Contact name

Mr Richard Ng

Contact details

Norgine House
Widewater Place
Moorhall Road
Uxbridge

United Kingdom
UB9 6NS
+44(0)1895453584
rng@norgine.com

Type(s)

Public

Contact name

Mr Jeff Pilot

Contact details

Norgine House
Widewater Place
Moorhall Road
Uxbridge
United Kingdom
UB9 6NS
+44(0)1895453736
jpilot@norgine.com

Additional identifiers

EudraCT/CTIS number

202200275639

IRAS number

1006328

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 1006328, 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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format

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 measure

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Secondary outcome measures

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Overall study start date

23/08/2022

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

Age group

Adult

Sex

Both

Target number of participants

126

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

England

United Kingdom

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

Sponsor information

Organisation

Norgine (United Kingdom)

Sponsor details

Norgine House
Widewater Place
Moorhill Road
Uxbridge
England
United Kingdom
UB9 6NS
+44(0)1895826600
clinicaltrials@norgine.com

Sponsor type

Industry

Website

<https://www.norgine.com>

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Norgine

Results and Publications

Publication and dissemination plan

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.

Intention to publish date

10/07/2026

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