ISRCTN28849775 https://doi.org/10.1186/ISRCTN28849775

Phase I Trial, Quotient Code: QSC300320

Submission date 23/09/2022	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol
Registration date 05/10/2022	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 14/02/2024	**Condition category** Other	[ ] Individual participant data [ ] 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
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
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
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 measure
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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
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