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

# Phase I Trial, Quotient Code: QSC300320

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

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## Additional identifiers

### Clinical Trials Information System (CTIS)
202200275639

### Integrated Research Application System (IRAS)
1006328

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
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

## Study type(s)
Other

## 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)
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.

## Primary outcome(s)
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.

## Key secondary outcome(s))
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.

## 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
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.

### 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
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# 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |