ISRCTN45504491 https://doi.org/10.1186/ISRCTN45504491

Phase I trial, Quotient Sciences code: QSC206403

Submission date 12/01/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/01/2023	**Overall study status** Deferred	
Last Edited 04/04/2023	**Condition category** Other	

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

EudraCT/CTIS number
2022-003288-10

IRAS number
1006587

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1006587, QSC206403

Study information

Scientific Title
Phase I trial, Quotient Sciences code: QSC206403 [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 13/03/2023, London Surrey Borders REC (London HRA Centre, 2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, UK; surreyborders.rec@hra.nhs.uk), ref: 23/LO/0006
2. Approved 13/03/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0)
20 3080 6000; info@mhra.gov.uk), ref: CTA 52215/0005/001-0001
The HRA has approved deferral of publication of trial details.

Study design
Pharmacokinetics trial

Primary study design
Interventional

Secondary study design
Pharmacokinetics trial

Study setting(s)
Pharmaceutical testing facility

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
22/12/2022

Completion date
27/07/2023

Eligibility

Key inclusion criteria
Healthy volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
12

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
24/04/2023

Date of final enrolment
27/07/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Quotient Sciences Limited
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Sponsor information

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Anavex Germany GmbH

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Anavex Germany GmbH

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. Results will be posted on or after the date of publication of full trial details.

Intention to publish date
27/01/2026

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 non-therapeutic 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