ISRCTN97798065 https://doi.org/10.1186/ISRCTN97798065

Phase I Trial, Quotient Code: QSC205947

Submission date 17/02/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/02/2023	**Overall study status** Deferred	
Last Edited 05/12/2023	**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.

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1006953

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1006953, Quotient Code: QSC205947

Study information

Scientific Title
Phase I Trial, Quotient Code: QSC205947 [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 03/04/2023, Wales REC 2 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2071048222, +44 (0)2920230457, +44 (0)

7920 565664; Wales.REC2@wales.nhs.uk); ref: 23/WA/0014.
2. Approved 03/04/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 57619/0001/001-0001

The HRA has approved deferral of publication of trial details.

Study design
Pharmacokinetics trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
No participant information sheet available

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
31/01/2023

Completion date
17/11/2023

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
20

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
04/04/2023

Date of final enrolment
17/11/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Quotient Sciences Limited
Mere Way
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Sponsor information

Organisation
Ventyx Biosciences, Inc.

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Sponsor type
Industry

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http://www.ventyxbio.com

Funder(s)

Funder type
Industry

Funder Name
Ventyx Biosciences, Inc.

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
17/05/2026

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