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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1006953

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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
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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

Study type(s)
Other

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(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
17/11/2023

Eligibility

Key inclusion criteria

Healthy human volunteer

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
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Date of first enrolment
04/04/2023

Date of final enrolment
17/11/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way
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Sponsor information

Organisation
Ventyx Biosciences, Inc.

Funder(s)

Funder type
Industry

Funder Name
Ventyx Biosciences, Inc.

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 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes