

Phase I Trial, Quotient Code: QSC205947

Submission date 17/02/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/02/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/12/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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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)

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Key secondary outcome(s)

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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

Ruddington Fields

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United Kingdom

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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