ISRCTN33084994 https://doi.org/10.1186/ISRCTN33084994

Phase I trial: QSC303485

Submission date 12/02/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/02/2026	**Overall study status** Deferred	
Last Edited 20/05/2026	**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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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1013141

Central Portfolio Management System (CPMS)
71400

CRO Study Code
QSC303485

Study information

Scientific Title
Phase I trial: QSC303485 (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
Ethics approval required

Ethics approval(s)
Approved 13/02/2026, Health and Social Care Research Ethics Committee (HSC REC) B (Office for Research Ethics Committees in Northern Ireland (ORECNI) Lissue Industrial Estate West 5 Rathdown Walk, Lisburn, BT28 2RF, United Kingdom; +44 (0)2895 361408; recb@hscni.net), ref: 26/NI/0002

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
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.

Purpose
Phase I study in healthy volunteers and patients

Study type(s)

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
1. [Outcome name] measured using [metric or method of measurement] at [timepoint(s)]

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Key secondary outcome(s)

Completion date
10/05/2027

Eligibility

Key inclusion criteria
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Healthy volunteers allowed
Yes

Age group

Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
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Date of first enrolment
24/02/2026

Date of final enrolment
10/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way, Ruddington Fields
Ruddington
Nottingham
England
NG11 6JS

Study participating centre
Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus, Hills Road
Cambridge
England
CB2 0QQ

Sponsor information

Organisation
Congruence Therapeutics Inc.

Funder(s)

Funder type

Funder Name
Congruence Therapeutics Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available