

Phase I trial: QSC303485

Submission date 12/02/2026	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/02/2026	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/05/2026	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" 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

Contact name

Dr Stuart Mair

Contact details

Mere Way, Ruddington Fields
Ruddington
Nottingham
United Kingdom
NG11 6JS
+44 (0)1159749000
recruitment@weneedyou.co.uk

Type(s)

Public, Scientific

Contact name

Dr Michael Harvey

Contact details

6666 Saint-Urbain Street
Suite 450
Montreal
Canada
H2S 3H1

+1 (0)4388173666
clinicaltrials@congruencetx.com

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

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

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**

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.

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)

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.

Primary outcome(s)

1. [Outcome name] measured using [metric or method of measurement] at [timepoint(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)**Completion date**

10/05/2027

Eligibility**Key inclusion 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.

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

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

24/02/2026

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