# Phase I trial, Quotient Code: QSC208063

Submission date	Recruitment status	[X] Prospectively registered
20/07/2023	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
11/08/2023	Deferred	Results
Last Edited	Condition category	Individual participant data
11/08/2023	Other	<ul><li>Record updated in last year</li></ul>

## 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 Phil Evans

#### Contact details

Quotient Sciences Limited
Mere Way
Ruddington Fields
Ruddington
Nottingham
United Kingdom
NG11 6JS
+44 (0)330 303 1000
Recruitment@weneedyou.co.uk

# Type(s)

Scientific

### Contact name

Dr Phil Evans

#### Contact details

Quotient Sciences Limited Mere Way Ruddington Fields Ruddington Nottingham United Kingdom NG11 6JS +44 (0)330 303 1000 Recruitment@weneedyou.co.uk

# Type(s)

Public

#### Contact name

Dr Regulatory Affairs

### Contact details

Quotient Sciences Limited
Mere Way
Ruddington Fields
Ruddington
Nottingham
United Kingdom
NG11 6JS
+44 (0)1159749000
regulatory.affairs@quotientsciences.com

# Additional identifiers

# Clinical Trials Information System (CTIS)

Nil known

# Integrated Research Application System (IRAS)

1007844

# ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

IRAS 1007844

# Study information

#### Scientific Title

Phase I trial, Quotient Code: QSC208063 [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)

submitted 21/06/2023, HSC REC B (c/o Office for Research Ethics Committees in Northern Ireland (ORECNI), Business Services Organisation, Lissue Industrial Estate West, Lisburn, Co. Antrim, BT28 2RF, United Kingdom; +44 (0)28 95361400; RECB@hscni.net), ref: 23/NI/0085

Submitted 21/06/2023, MHRA (10 South Colonnade, Canary Wharf, London E14 4PU, UK; +44 (0) 20 3080 6000; info@mhra.gov.uk), ref: CTA 42285/0004/001-0001

## Study design

Three-part single-centre randomized study to assess pharmacokinetics, relative bioavailability, safety and tolerability in 72 healthy volunteers

## Primary study design

Interventional

## Study type(s)

Other

## 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)

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# 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

29/12/2024

# Eligibility

# Key inclusion criteria

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# Participant type(s)

Healthy volunteer

# Healthy volunteers allowed

No

## Age group

Adult

#### Sex

All

## Key exclusion criteria

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### Date of first enrolment

04/09/2023

### Date of final enrolment

29/12/2024

# Locations

### Countries of recruitment

United Kingdom

England

# Study participating centre Quotient Sciences Limited

Mere Way Ruddington Fields Ruddington Nottingham United Kingdom NG11 6JS

# **Sponsor information**

## Organisation

Trevena, Inc.

# Funder(s)

## Funder type

Industry

#### **Funder Name**

Trevena, 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