

# Phase I trial, Quotient Code: QSC208063

<b>Submission date</b> 20/07/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/08/2023	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/08/2023	<b>Condition category</b> 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

### Contact name

Dr Phil Evans

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### Type(s)

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**Type(s)**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

1007844

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Pharmaceutical testing facility

**Study type(s)**

Other

**Participant information sheet**

Not available in web format

**Health condition(s) or problem(s) studied**

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**Interventions**

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**Intervention Type**

Drug

**Pharmaceutical study type(s)**

Pharmacokinetic

**Phase**

Phase I

**Drug/device/biological/vaccine name(s)**

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### **Primary outcome measure**

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### **Secondary outcome measures**

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### **Overall study start date**

21/06/2023

### **Completion date**

29/12/2024

## **Eligibility**

### **Key inclusion criteria**

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### **Participant type(s)**

Healthy volunteer

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

72

### **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

England

United Kingdom

## Study participating centre

### Quotient Sciences Limited

Mere Way

Ruddington Fields

Ruddington

Nottingham

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# Sponsor information

## Organisation

Trevena, Inc.

## Sponsor details

955 Chesterbrook Blvd. Suite 110

Chesterbrook

United States of America

PA 19087

+1 (0)610 354 8840

mdemitrack@trevena.com

## Sponsor type

Industry

## Website

<https://www.trevena.com>

# Funder(s)

## Funder type

Industry

## Funder Name

Trevena, Inc.

# Results and Publications

## Publication and dissemination plan

Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this phase I study and the negligible benefit to the public of phase I information. Results will be posted on or after the date of publication of full trial details.

## Intention to publish date

29/06/2027

## 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