

# 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)

Scientific

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### **Type(s)**

Public

### **Contact name**

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## **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

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# 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