

Phase I trial, Quotient Code: QSC208063

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

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1007844

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