ISRCTN17473850 https://doi.org/10.1186/ISRCTN17473850

Phase I trial, Quotient Code: QSC208063

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

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

Integrated Research Application System (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
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)
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

Primary study design
Interventional

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

Study type(s)
Other

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)
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)
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
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.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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