ISRCTN31420409 https://doi.org/10.1186/ISRCTN31420409

Phase I Trial: Quotient Code QSC300687

Submission date 28/05/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/05/2024	**Overall study status** Deferred	
Last Edited 21/06/2024	**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 Nand Singh

Contact details
Mere Way, Ruddington
Nottingham
United Kingdom
NG11 6JS
+44 (0)330 303 1000
recruitment@weneedyou.co.uk

Type(s)
Public, Scientific

Contact name
Ms Kavita Dhamdhere

Contact details
15440 Laguna Canyon Road, Suite 160
Irvine
United States of America
CA 92618

Type(s)

Public, Scientific

Contact name
Ms Alisa Hewitt

Contact details
15440 Laguna Canyon Road, Suite 160
Irvine
United States of America
CA 92618

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1008711

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 1008711, Quotient Code: QSC300687

Study information

Scientific Title
Phase I Trial: Quotient Code QSC300687

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 30/04/2024, London - Surrey Borders REC (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; + 44 (0) 20 7104 8057; surreyborders.rec@hra.nhs.uk), ref: 24/LO/0231

Study design
Mass balance recovery pharmacokinetic metabolite profiling and identification and safety and tolerability study

Primary study design
Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied
Healthy volunteers

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
18/01/2025

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
Male

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
02/07/2024

Date of final enrolment
18/01/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way, Ruddington
Nottingham
United Kingdom
NG11 6JS

Sponsor information

Organisation
Tarsus Pharmaceuticals, Inc.

Funder(s)

Funder type
Industry

Funder Name
Tarsus Pharmaceuticals, 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