# Phase I Trial: Quotient Code QSC302246

Submission date	Recruitment status	[X] Prospectively registered
05/11/2025	Not yet recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
05/11/2025	Deferred	Results
Last Edited	<b>Condition category</b> Not Specified	☐ Individual participant data
07/11/2025		[X] 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. 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

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, Scientific

#### Contact name

Mr David McCoubrey

#### Contact details

Galen Limited, Seagoe Industrial Estate Craigavon United Kingdom BT63 5UA 028 3833 4974 regulatoryaffairs@almacgroup.com

## Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### Integrated Research Application System (IRAS)

1012925

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

Quotient code QSC302246

# Study information

#### Scientific Title

Phase I Study: Quotient Code QSC302246 [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 29/09/2025, London – Surrey Borders Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)20 7972 8143; surreyborders.rec@hra.nhs.uk), ref: 25/LO/0653

## Study design

Bioavailability and pharmacokinetic study in healthy volunteers.

# Primary study design

Interventional

## 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

06/01/2026

# **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. Full details will be added to the study record within 30 months after the trial has ended.

Date of first enrolment 28/11/2025

Date of final enrolment 20/12/2025

## 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

Galen Limited

# Funder(s)

Funder type

Not defined

**Funder Name** 

Galen Limited

# **Results and Publications**

## Individual participant data (IPD) sharing plan

Not expected to be made available

## 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 No Yes