

Phase I Study: Quotient Code QSC303294

Submission date 10/11/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/11/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/02/2026	Condition category Not Specified	<input type="checkbox"/> Individual participant data <input checked="" 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. Full details will be added to the study record within 30 months after the trial has ended.

Contact information

Type(s)

Principal investigator

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Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1012558

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Quotient Code QSC303294

Study information

Scientific Title

Phase I Study: Quotient Code QSC303294

Study objectives

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Ethics approval required

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Ethics approval(s)

1. approved 06/11/2025, London - Surrey Borders (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 20 7972 8143; surreyboundaries.rec@hra.nhs.uk), ref: 25/LO/0648
2. approved 06/11/2025, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 21566/0225/001-0001

Study design

Two-part study to evaluate pharmacokinetics of formulations in 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. Full details will be added to the study record within 30 months after the trial has ended.

Completion date

03/07/2026

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

55 years

Sex

All

Total final enrolment

0

Key exclusion criteria

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Date of first enrolment

18/11/2025

Date of final enrolment

03/07/2026

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**Quotient Sciences Limited**

Mere Way, Ruddington Fields, Ruddington, Nottingham

Nottingham

England

NG11 6JS

Sponsor information**Organisation**

BIAL Portela & Ca. S.A.

Funder(s)**Funder type**

Industry

Funder Name

BIAL Portela & Ca. S.A.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available