ISRCTN16910437 https://doi.org/10.1186/ISRCTN16910437

Phase I Study: Quotient Code QSC303294

Submission date 10/11/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/11/2025	**Overall study status** Deferred	
Last Edited 13/11/2025	**Condition category** Not Specified	

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.

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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
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)
1. approved 06/11/2025, London - Surrey Borders (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 20 7972 8143; surreyborders.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)
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.

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
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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

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