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Phase I Trial: Quotient Code QSC303217

Submission date 24/06/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 01/07/2025	**Overall study status** Deferred	
Last Edited 01/07/2025	**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. Full details will be added to the study record within 30 months after the trial has ended.

Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1011885

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Sponsor Code: AVK-101-102, Quotient Code: QSC303217

Study information

Scientific Title
Phase I Trial: Quotient Code QSC303217

Study objectives
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.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/06/2025, London – Hampstead Regulatory Ethics Committee (REC) (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8171; hampstead.rec@hra.nhs.uk), ref: 25/LO/0198

Study design
Two-part single-centre mass balance recovery and food effect study 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
22/08/2025

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
65 years

Sex
All

Key exclusion criteria
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Date of first enrolment
01/07/2025

Date of final enrolment
22/08/2025

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
Aardvark Therapeutics, Inc.

Funder(s)

Funder type
Industry

Funder Name
Aardvark Therapeutics, 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