ISRCTN11329248 https://doi.org/10.1186/ISRCTN11329248

Phase I Trial: Quotient Code QSC303217

Submission date 24/06/2025	**Recruitment status** 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

Type(s)
Public, Scientific

Contact name
Dr Terrie Kellmeyer

Contact details
Aardvark Therapeutics, Inc., 4370 La Jolla Village Drive, Suite 1050
San Diego
United States of America
92122
+1 (858) 225-7696
Info@AardvarkTherapeutics.com

Type(s)
Principal Investigator

Contact name
Dr David Everton

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

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1011885

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Partially randomised study

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
30/04/2025

Completion date
22/08/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
20

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
England

United Kingdom

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

Sponsor information

Organisation
Aardvark Therapeutics, Inc.

Sponsor details
4370 La Jolla Village Drive
Suite 1050
San Diego
United States of America
92122
+1 (858) 225-7696
Info@AardvarkTherapeutics.com

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Aardvark Therapeutics, Inc.

Results and Publications

Publication and dissemination plan
Full trial details will be published up to 30 months after the end of the trial. Publication of some of the trial details is deferred because of the high commercial sensitivity of this Phase I study and the negligible benefit to the public of Phase I information. Results may be posted on or after the date of publication of trial details.

Intention to publish date
22/02/2028

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