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

# Phase I Trial: Quotient Code QSC303217

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| **Submission date**<br>24/06/2025 | **Recruitment status**<br>Recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>01/07/2025 | **Overall study status**<br>Deferred | |
| **Last Edited**<br>01/07/2025 | **Condition category**<br>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
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.

### Interventions
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.

### Intervention Type
Drug

### Pharmaceutical study type(s)
Pharmacokinetic

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

### 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
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.

**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**
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**
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