ISRCTN13265717 https://doi.org/10.1186/ISRCTN13265717

Phase 1 trial: Labcorp code 8501022

Submission date 21/03/2023	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 23/03/2023	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 30/10/2023	**Condition category** Other	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
The Health Research Authority (HRA) has approved 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.

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1006499

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1006499, Labcorp code: 8501022

Study information

Scientific Title
Phase 1 trial: Labcorp code 8501022

Study objectives
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Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Approved 21/12/2022, North East - York Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0) 207 104 8079; york.rec@hra.nhs.uk), ref: 22/NE/0185
2. Approved 17/01/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0) 20 3080 6000; info@mhra.gov.uk), ref: CTA 36216/0012/001-0001

The HRA has approved deferral of publication of trial details.

Study design
Safety and tolerability study in 108 healthy volunteers.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
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Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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Secondary outcome measures
The Health Research Authority (HRA) has approved 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.

Overall study start date
23/09/2022

Completion date
26/09/2023

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
108

Total final enrolment
76

Key exclusion criteria
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Date of first enrolment
06/02/2023

Date of final enrolment
26/09/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Labcorp CRU Ltd
Springfield House
Hyde Street
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Sponsor information

Organisation
Albireo (Sweden)

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Sponsor type
Industry

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ROR
https://ror.org/02py10784

Funder(s)

Funder type

Industry

Funder Name
Albireo AB

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 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 will be posted on or after the date of publication of full trial details.

Intention to publish date
04/04/2026

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?
HRA research summary			26/07/2023	No	No