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

Type(s)
Principal investigator

Contact name
Dr Firas Almazedi

Contact details
Drapers Yard
Marshall Street
Holbeck
Leeds
United Kingdom
LS11 9EH
+44 (0)113 301 3642
firas.almazedi@labcorp.com

Type(s)
Public

Contact name
Dr Firas Almazedi

Contact details
Drapers Yard
Marshall Street
Holbeck
Leeds

United Kingdom
LS11 9EH
+44 (0)113 301 3642
firas.almazedi@labcorp.com

Type(s)
Scientific

Contact name
Dr Firas Almazedi

Contact details
Drapers Yard
Marshall Street
Holbeck
Leeds
United Kingdom
LS11 9EH
+44 (0)113 301 3642
firas.almazedi@labcorp.com

Additional identifiers

Integrated Research Application System (IRAS)
1006499

Protocol serial number
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.

Primary study design
Interventional

Study design
Safety and tolerability study in 108 healthy volunteers.

Study type(s)
Other

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(s)
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Key secondary outcome(s)
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.

Completion date
26/09/2023

Eligibility

Key inclusion criteria
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Participant type(s)

Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Labcorp CRU Ltd
Springfield House
Hyde Street
Leeds
United Kingdom
LS2 9LH

Study participating centre
Labcorp CRU Ltd
Drapers Yard, Marshall Street
Holbeck
Leeds
United Kingdom
LS11 9EH

Sponsor information

Organisation
Albireo (Sweden)

ROR
https://ror.org/02py10784

Funder(s)

Funder type
Industry

Funder Name
Albireo AB

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?
HRA research summary			26/07/2023	No	No