

Phase 1 trial: Labcorp code 8501022

Submission date 21/03/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/03/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/10/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 Almazed

Contact details

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

Type(s)

Public

Contact name

Dr Firas Almazed

Contact details

Drapers Yard
Marshall Street
Holbeck
Leeds

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

Type(s)
Scientific

Contact name
Dr Firas Almazedil

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

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

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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
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)

Sponsor details

Arvid Wallgrens backe 20
Göteborg
Sweden
41346
+46 31 741 14 80
medinfo@albireopharma.com

Sponsor type

Industry

Website

<https://albireopharma.com/>

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