

Phase I trial: Labcorp Drug Development Study: 8479217

Submission date 28/09/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/10/2022	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/10/2022	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 Ashley Brooks

Contact details

Labcorp Clinical Research Unit
Springfield House, Hyde Street
Leeds
United Kingdom
LS2 9LH
+44 (0)113 301 3521
ashley.brooks@labcorp.com

Type(s)

Scientific

Contact name

Dr Ashley Brooks

Contact details

Labcorp Clinical Research Unit
Springfield House, Hyde Street
Leeds

United Kingdom
LS2 9LH
+44 (0) 113 301 3521
ashley.brooks@labcorp.com

Type(s)

Public

Contact name

Dr Ashley Brooks

Contact details

Labcorp Clinical Research Unit
Springfield House, Hyde Street
Leeds
United Kingdom
LS2 9LH
+44 (0) 113 301 3521
ashley.brooks@labcorp.com

Additional identifiers

Clinical Trials Information System (CTIS)

202100563124

Integrated Research Application System (IRAS)

1004924

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 1004924, Labcorp Drug Development Study 8479217

Study information

Scientific Title

Phase I trial: Labcorp Drug Development Study: 8479217 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives

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Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/07/2022, MHRA and HRA Fast track REC (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0)207 104 8012; fasttrack.rec@hra.nhs.uk), ref: CTA 42371/0009/001-0001, REC ref: 22/FT/0036

The HRA has approved deferral of publication of trial details.

Study design

A mass balance study and metabolic profile investigation

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

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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)

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Completion date

16/09/2022

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

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Date of first enrolment

02/08/2022

Date of final enrolment

16/09/2022

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Labcorp Clinical Research Unit Limited

Springfield House

Hyde Street

Leeds

United Kingdom

LS2 9LH

Sponsor information

Organisation
Bergenbio ASA

Funder(s)

Funder type
Industry

Funder Name
Bergenbio ASA

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			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes