# Phase I trial: Labcorp Drug Development Study: 8479217

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
28/09/2022		<pre>Protocol</pre>		
Registration date 14/10/2022	Overall study status Deferred	Statistical analysis plan		
		Results		
<b>Last Edited</b> 14/10/2022	<b>Condition category</b> Other	Individual participant data		
		<ul><li>Record updated in last year</li></ul>		

# 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

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# Type(s)

Scientific

#### Contact name

Dr Ashley Brooks

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# Type(s)

**Public** 

#### Contact name

Dr Ashley Brooks

#### Contact details

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# Additional identifiers

# **EudraCT/CTIS** number

202100563124

#### IRAS number

1004924

#### ClinicalTrials.gov number

Nil known

# Secondary identifying numbers

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

#### Secondary study design

Non randomised study

#### Study setting(s)

Other

#### Study type(s)

Other

#### Participant information sheet

Not available in web format

# 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)

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.

#### 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

16/05/2022

#### Completion date

16/09/2022

# **Eligibility**

# Key inclusion criteria

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#### Participant type(s)

Healthy volunteer

#### Age group

Adult

#### Sex

Both

# Target number of participants

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# 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

England

United Kingdom

# Study participating centre Labcorp Clinical Research Unit Limited

Springfield House Hyde Street Leeds United Kingdom LS2 9LH

# Sponsor information

#### Organisation

Bergenbio ASA

## Sponsor details

Jonas Lies vei 91 Bergen Norway 5009 +44 (0)7810 575 037 post@bergenbio.com

#### Sponsor type

Industry

# Funder(s)

# Funder type

Industry

#### **Funder Name**

Bergenbio ASA

# **Results and Publications**

## Publication and dissemination plan

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

16/03/2025

# 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