

# Phase I trial: Royal Infirmary Edinburgh Clinical Research Facility code: 003

<b>Submission date</b> 13/10/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/10/2022	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/11/2022	<b>Condition category</b> 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 David Newby

### Contact details

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## Additional identifiers

### EudraCT/CTIS number

2021-00196920

### IRAS number

1004538

### ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

IRAS 1004538, CPMS 51275

# Study information

## Scientific Title

Phase I trial: Royal Infirmary Edinburgh Clinical Research Facility code: 003 [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)

1. Approved 31/01/2022, North East - York Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048091; york.rec@hra.nhs.uk), ref: 22/NE/0004
2. Approved 09/02/2022, Medicines & Healthcare products Regulatory Agency (MHRA) (10 South Colonnade, Canary Wharf, London, E14 4PU, UK, +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 55892/0001/001

The HRA has approved deferral of publication of trial details.

## Study design

First-in-human single-ascending-dose multiple-ascending-dose study

## Primary study design

Interventional

## Secondary study design

Randomized trial

## 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**

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**Overall study start date**

27/01/2022

**Completion date**

15/04/2023

**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**

29/10/2021

### **Date of final enrolment**

15/04/2023

## **Locations**

### **Countries of recruitment**

United Kingdom

### **Study participating centre**

-

United Kingdom

-

## **Sponsor information**

### **Organisation**

Vifor (International) Inc.

### **Sponsor details**

Rechenstrasse 37

St. Gallen

Switzerland

9014

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. Deferral was approved on 25 May 2022. The full details will be added to the study record within 30 months after the trial has ended.

[transparency@viforpharma.com](mailto:transparency@viforpharma.com)

### **Sponsor type**

Industry

### **Website**

<http://www.viforpharma.com/en/>

# Funder(s)

## Funder type

Industry

## Funder Name

Vifor (International) Inc.

# 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

15/10/2025

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No