ISRCTN76722400 https://doi.org/10.1186/ISRCTN76722400

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

Submission date	Recruitment status	[ ] Prospectively registered
13/10/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/10/2022	Deferred	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/11/2022	Other	[ ] 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
Royal Infirmary Edinburgh Clinical Research Facility
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA
0131 242 7183
info@edinburghcrf.ed.ac.uk

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
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.

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
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

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?
HRA research summary			28/06/2023	No	No