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

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Additional identifiers

Clinical Trials Information System (CTIS)
2021-00196920

Integrated Research Application System (IRAS)
1004538

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

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)
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.

Key secondary outcome(s))
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Completion date
15/04/2023

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
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.

Funder(s)

Funder type
Industry

Funder Name
Vifor (International) Inc.

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

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