Phase I trial HMR code: 23-503

Submission date	Recruitment status	[X] Prospectively registered
31/01/2024	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
15/02/2024	Deferred	Results
Last Edited	Condition category	Individual participant data
02/05/2024	Other	Record updated in last year

Plain English summary of protocol

The sponsor has confirmed that the trial meets the criteria for 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 Denisa Wilkes

Contact details

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Type(s)

Public

Contact name

Dr Reception Department

Contact details

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Type(s)

Scientific

Contact name

Dr Denisa Wilkes

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1008987

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 1008987, HMR code: 23-503

Study information

Scientific Title

Phase I trial HMR code: 23-503 [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

Ethics approval required

Ethics approval(s)

1. approved 23/01/2024, North East - York Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8052; york.rec@hra.nhs.uk), ref: 23/NE/0206

2. approved 12/02/2024, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: -

Study design

First-in-human safety, pharmacokinetics and pharmacodynamics trial in up to 220 healthy volunteers and patients

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 sponsor has confirmed that the trial meets the criteria for 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))

The sponsor has confirmed that the trial meets the criteria for 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.

Completion date

30/06/2026

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer, Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

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Date of first enrolment

20/02/2024

Date of final enrolment

31/03/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Hammersmith Medicines Research (HMR) Limited

Cumberland Avenue London United Kingdom NW10 7EW

Sponsor information

Organisation

Funder(s)

Funder type

Industry

Funder Name

Nxera Pharma UK Ltd

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?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes