

Phase I trial HMR code: 23-503

Submission date 31/01/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/02/2024	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/03/2026	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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, Scientific

Contact name

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Type(s)

Public

Contact name

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Contact details

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Additional identifiers

Integrated Research Application System (IRAS)
1008987

Protocol serial number
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

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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)

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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

Total final enrolment

0

Key exclusion criteria

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Date of first enrolment

20/02/2024

Date of final enrolment

24/12/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Hammersmith Medicines Research (HMR) Limited

Cumberland Avenue

London

England

NW10 7EW

Sponsor information

Organisation

Nxera Pharma UK Ltd

Funder(s)

Funder type

Industry

Funder Name

Nxera Pharma UK Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available