ISRCTN70080074 https://doi.org/10.1186/ISRCTN70080074

Phase I trial HMR code: 23-503

Submission date 31/01/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 15/02/2024	**Overall study status** Deferred	
Last Edited 25/03/2026	**Condition category** Other	

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

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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
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.

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: -

Primary study design
Interventional

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

Study type(s)
Other

Health condition(s) or problem(s) studied
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Interventions

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.

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

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