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

Phase I trial HMR code: 23-503

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

EudraCT/CTIS number
Nil known

IRAS number
1008987

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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
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: -

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

Primary study design
Interventional

Secondary study design
Randomized controlled trial; randomized cross over 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
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

Pharmaceutical study type(s)
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Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure

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Secondary outcome measures
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.

Overall study start date
24/11/2023

Completion date
30/06/2026

Eligibility

Key inclusion criteria
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.

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Sex
Both

Target number of participants
Up to 220

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
England

United Kingdom

Study participating centre
Hammersmith Medicines Research (HMR) Limited
Cumberland Avenue
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Sponsor information

Organisation
Nxera Pharma UK Ltd

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Nxera Pharma UK Ltd

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 1 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
30/12/2028

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