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

HMR, Cumberland Avenue London United Kingdom NW10 7EW +44 (0)20 8961 4130 rec@hmrlondon.com

Type(s)

Public

Contact name

Dr Reception Department

Contact details

Nxera Pharma UK Ltd Steinmetz Building Granta Park Great Abington Cambridge United Kingdom CB21 6DG +44 (0)1223 949 100 reception@nxera.life

Type(s)

Scientific

Contact name

Dr Denisa Wilkes

Contact details

HMR, Cumberland Avenue London United Kingdom NW10 7EW +44 (0)20 8961 4130 rec@hmrlondon.com

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

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.

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)

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.

Phase

Phase I

Drug/device/biological/vaccine name(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.

Primary outcome measure

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.

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

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.

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
London
United Kingdom
NW10 7EW

Sponsor information

Organisation

Nxera Pharma UK Ltd

Sponsor details

Steinmetz Building Granta Park Great Abington Cambridge England United Kingdom CB21 6DG +44 (0)1223 949 100 reception@nxera.life

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