ISRCTN17231793 https://doi.org/10.1186/ISRCTN17231793

Phase I trial, HMR code: 22-016

Submission date 30/05/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/06/2023	**Overall study status** Deferred	
Last Edited 18/04/2024	**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

Type(s)
Principal investigator

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1007377

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 1007377, HMR code: 22-016

Study information

Scientific Title
Phase I trial, HMR code: 22-016 [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
Old ethics approval format

Ethics approval(s)
1. Approved 25/05/2023, London – Brent Research Ethics Committee (80 London Road, Skipton House, SE1 6LH, UK; +44 (0)207 104 8137; brent.rec@hra.nhs.uk), ref: 23/LO/0154
2. Approved 15/06/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 42719/0014/001-0001

Study design
First-in-human safety, pharmacokinetics and pharmacodynamics trial in up to 104 heathy volunteers

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Healthy volunteers

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
29/11/2024

Eligibility

Key inclusion criteria
Healthy volunteer

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

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Date of first enrolment
16/06/2023

Date of final enrolment
15/08/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Medicines Research (HMR)
Cumberland Avenue
London
United Kingdom
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

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