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

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Principal Investigator

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1007377

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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
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
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

Secondary study design
Randomized controlled; parallel; partial crossover; open-label, crossover trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format

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

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)
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
20/02/2023

Completion date
29/11/2024

Eligibility

Key inclusion criteria

Healthy volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
Up to 104

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
16/06/2023

Date of final enrolment
15/08/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hammersmith Medicines Research (HMR)
Cumberland Avenue
London
United Kingdom
NW10 7EW

Sponsor information

Organisation
Nxera Pharma UK Ltd

Sponsor details

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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 I 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
29/05/2027

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