

Phase I trial, HMR code: 22-016

Submission date 30/05/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/06/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/04/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 Steve Warrington

ORCID ID

<https://orcid.org/0000-0003-1602-4536>

Contact details

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

Type(s)

Scientific

Contact name

Dr Steve Warrington

Contact details

HMR, Cumberland Avenue
London
United Kingdom

NW10 7EW
+44 (0)20 8961 4130
rec@hmrlondon.com

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 healthy 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)

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Key secondary outcome(s)

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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