

Phase I trial: HMR code: 24-001

Submission date 17/09/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/10/2024	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/03/2026	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" 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, Scientific

Contact name

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Contact details

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Additional identifiers

Integrated Research Application System (IRAS)
1010262

Protocol serial number
HMR Code: 24-001

Study information

Scientific Title

Phase I trial: HMR code: 24-001 [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
Ethics approval required

Ethics approval(s)

approved 16/07/2024, London - Brent Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 107 8117; brent.rec@hra.nhs.uk), ref: 24/LO/0430

Study design

A randomized, placebo-controlled crossover MRI interventional study involving a caffeine challenge

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

15/11/2025

Eligibility**Key inclusion criteria**

Healthy human volunteers

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

0

Key exclusion criteria

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Date of first enrolment

21/10/2024

Date of final enrolment

15/08/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

King's College London

Centre for Neuroimaging Sciences PO89

Institute of Psychiatry, Psychology and Neuroscience (IoPPN)

De Crespigny Park

London

England

SE5 8AF

Sponsor information

Organisation

Nxera Pharma UK Limited

Funder(s)

Funder type

Industry

Funder Name

Nxera Pharma UK Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available