ISRCTN44913564 https://doi.org/10.1186/ISRCTN44913564

Phase I trial: HMR code: 24-001

Submission date 17/09/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 01/10/2024	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 25/03/2026	**Condition category** Other	[_] Individual participant data [X] 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

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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

Primary study design
Interventional

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

Study type(s)
Other

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

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(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
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
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

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
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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