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

Phase I trial: HMR code: 24-001

Submission date 17/09/2024	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 01/10/2024	**Overall study status** Deferred	
Last Edited 05/11/2024	**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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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1010262

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1010262, 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
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
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

Secondary study design
Randomised controlled 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
07/06/2024

Completion date
15/11/2025

Eligibility

Key inclusion criteria
Healthy human volunteers

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
24

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
England

United Kingdom

Study participating centre
King's College London
Centre for Neuroimaging Sciences PO89
Institute of Psychiatry, Psychology and Neuroscience (IoPPN)
De Crespigny Park
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Sponsor information

Organisation
Nxera Pharma UK Limited

Sponsor details
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Nxera Pharma UK Limited

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 may be posted on or after the date of publication of full trial details.

Intention to publish date
15/05/2028

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