

# Phase I trial: HMR code: 24-001

<b>Submission date</b> 17/09/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/10/2024	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/11/2024	<b>Condition category</b> 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 Ndabezinhle Mazibuko

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

1010262

### ClinicalTrials.gov (NCT)

Nil known

**Protocol serial number**

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**

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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)**

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

**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  
United Kingdom  
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

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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes