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

# Phase I trial: HMR code: 24-001

Submission date 17/09/2024	<b>Recruitment status</b> Recruiting	[X] Prospectively registered [_] Protocol
<b>Registration date</b> 01/10/2024	<b>Overall study status</b> Deferred	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 05/11/2024	<b>Condition category</b> Other	<ul> <li>Individual participant data</li> <li>[X] Record updated in last year</li> </ul>

#### 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**

Centre for Neuroimaging Sciences PO89 Institute of Psychiatry, Psychology and Neuroscience (IoPPN) De Crespigny Park London United Kingdom SE5 8AF +44 (0)20 3228 3047 peter.hawkins@kcl.ac.uk

### 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)

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.

#### 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

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** 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 London United Kingdom SE5 8AF

### Sponsor information

**Organisation** Nxera Pharma UK Limited

#### Sponsor details

Steinmetz Building Granta Park Cambridge England United Kingdom CB21 6DG +44 (0)1223 949 100 reception@nxera.life

#### 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