

Phase I trial: HMR code: 24-001

Submission date 17/09/2024	Recruitment status 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 05/11/2024	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

Contact name

Dr Ndabezinhle Mazibuko

Contact details

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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

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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

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

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Intervention Type

Drug

Pharmaceutical study type(s)

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Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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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

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

Nxera Pharma UK Limited

Sponsor details

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Granta Park

Cambridge

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+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