# Phase 1 trial HMR code: 22-017

Submission date	Recruitment status	[X] Prospectively registered
26/05/2023	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
03/08/2023	Deferred	Results
Last Edited	Condition category	Individual participant data
15/05/2025	Other	[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

# Type(s)

Principal Investigator

#### Contact name

Dr Steve Warrington

#### **ORCID ID**

http://orcid.org/0000-0003-1602-4536

#### Contact details

HMR, Cumberland Avenue London United Kingdom NW10 7EW +44 (0)208 961 4130 rec@hmrlondon.com

#### Type(s)

Scientific

#### Contact name

Mr Clinical Development Lead

#### Contact details

Neurocrine Biosciences, Inc. 12780 El Camino Real San Diego United States of America CA 92130 +1-877-641-3461 medinfo@neurocrine.com

# Additional identifiers

## **EudraCT/CTIS** number

Nil known

#### IRAS number

1007409

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

IRAS 1007409; HMR code: 22-017

# Study information

#### Scientific Title

Phase 1 trial HMR code: 22-017

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)

- 1. Approved 12/06/2023, London Brent Research Ethics Committee (80 London Road, Skipton House, London, SE1 6LH, United Kingdom; +44 (0)207 104 8128; brent.rec@hra.nhs.uk), ref: 23 /LO/0178 2
- 2. Approved 27/07/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 17346/0212/001-0001

#### Study design

Phase I study

# Primary study design

Interventional

#### Secondary study design

Randomised controlled, randomized crossover, randomized parallel

#### 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

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

10/03/2023

#### Completion date

05/12/2024

# **Eligibility**

## Key inclusion criteria

Healthy human volunteers

# Participant type(s)

Healthy volunteer

#### Age group

Adult

#### Sex

Both

# Target number of participants

Up to 134

# Key exclusion criteria

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## Date of first enrolment

08/08/2023

#### Date of final enrolment

17/01/2024

# Locations

# Countries of recruitment

England

United Kingdom

# Study participating centre Hammersmith Medicines Research (HMR)

Cumberland Avenue London United Kingdom NW10 7EW

# Sponsor information

# Organisation

Neurocrine Biosciences (United States)

#### Sponsor details

12780 El Camino Real San Diego United States of America CA 92130 +1-877-641-3461 medinfo@neurocrine.com

# Sponsor type

Industry

#### **ROR**

https://ror.org/05d84mm26

# Funder(s)

# Funder type

Industry

#### **Funder Name**

**Neurocrine Biosciences** 

# Alternative Name(s)

Neurocrine Biosciences, Inc.

#### Funding Body Type

Government organisation

## **Funding Body Subtype**

For-profit companies (industry)

#### Location

United States of America

# **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 1 study and the negligible benefit to the public of phase 1 information. Results will be posted on or after the date of publication of full trial details.

# Intention to publish date

05/06/2027

# 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