

Phase 1 trial HMR code: 22-017

Submission date 26/05/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/08/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/05/2025	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

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Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1007409

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

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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

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

05/12/2024

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

08/08/2023

Date of final enrolment

17/01/2024

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Hammersmith Medicines Research (HMR)

Cumberland Avenue

London

United Kingdom

NW10 7EW

Sponsor information

Organisation

Neurocrine Biosciences (United States)

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

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