ISRCTN51803225 https://doi.org/10.1186/ISRCTN51803225

Phase 1 trial HMR code: 22-017

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

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

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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
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)
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
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)
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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
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
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
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
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NW10 7EW

Sponsor information

Organisation
Neurocrine Biosciences (United States)

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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