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
Registration date 03/08/2023	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 15/05/2025	**Condition category** Other	[_] Individual participant data [_] 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

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Additional identifiers

Integrated Research Application System (IRAS)
1007409

Protocol serial number
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

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)
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.

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