ISRCTN34662787 https://doi.org/10.1186/ISRCTN34662787

Phase 1 trial HMR code: 22-006

Submission date 13/07/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/07/2022	**Overall study status** Deferred	
Last Edited 08/02/2023	**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

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2022-001954-47

IRAS number
1005897

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

IRAS 1005897, HMR code: 22-006

Study information

Scientific Title
Phase 1 trial HMR code: 22-006
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
Old ethics approval format

Ethics approval(s)
1. Approved 26/07/2022 London – Brent Research Ethics Committee (80 London Road, Skipton House, SE1 6LH, United Kingdom; +44 (0)207 1048137; brent.rec@hra.nhs.uk), ref: 22/LO/0430
2. Approved 26/07/2022 MHRA (10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 42719/0013/001-0001

Study design
Pharmacokinetic-interaction open-label crossover study

Primary study design
Interventional

Secondary study design
Open-label crossover study

Study setting(s)
Pharmaceutical testing facility

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

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
15/06/2022

Completion date
26/12/2022

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
Up to 16

Key exclusion criteria
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Date of first enrolment
29/07/2022

Date of final enrolment

25/09/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
HMR
Cumberland Avenue, Park Royal
London
United Kingdom
NW10 7EW

Sponsor information

Organisation
Heptares Therapeutics (United Kingdom)

Sponsor details
Steinmetz Building
Granta Park
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CB21 6DG
+44 (0)1223 949 100
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Sponsor type
Industry

Website
http://www.heptares.com/

ROR
https://ror.org/051fk5x88

Funder(s)

Funder type

Industry

Funder Name
Heptares Therapeutics (United Kingdom)

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
26/06/2025

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