

Phase 1 trial HMR code: 22-006

Submission date 13/07/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/07/2022	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/02/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input 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)

Scientific

Contact name

Dr Temitope Fadeke

Contact details

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Additional identifiers

EudraCT/CTIS number

2022-001954-47

IRAS number

1005897

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Study information

Scientific Title

Phase 1 trial HMR code: 22-006

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Study objectives

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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

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Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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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

Cambridge

England

United Kingdom

CB21 6DG

+44 (0)1223 949 100

reception@soseiheptares.com

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