

# Phase 1 trial HMR code: 22-006

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

### Clinical Trials Information System (CTIS)

2022-001954-47

### Integrated Research Application System (IRAS)

1005897

### Protocol serial number

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

## 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**

26/12/2022

## **Eligibility**

### **Key inclusion criteria**

Healthy human volunteer

### **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**

29/07/2022

### **Date of final enrolment**

25/09/2022

## **Locations**

### **Countries of recruitment**

United Kingdom

England

## **Study participating centre**

**HMR**

Cumberland Avenue, Park Royal  
London  
United Kingdom  
NW10 7EW

## **Sponsor information**

### **Organisation**

Heptares Therapeutics (United Kingdom)

### **ROR**

<https://ror.org/051fk5x88>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Heptares Therapeutics (United Kingdom)

## **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