ISRCTN12926361 https://doi.org/10.1186/ISRCTN12926361

# Phase 1 trial, HMR code: 21-004

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|---|---|---|
| **Submission date**<br>09/03/2022 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol |
| **Registration date**<br>24/03/2022 | **Overall study status**<br>Deferred | [ ] Statistical analysis plan<br>[ ] Results |
| **Last Edited**<br>24/03/2022 | **Condition category**<br>Not Specified | [ ] Individual participant data<br>[ ] Record updated in last year |

**Plain English summary of protocol**
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record when the results are published, which will be within 30 months after the trial has ended.

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**
2021-001912-26

**Integrated Research Application System (IRAS)**
1003759

**Protocol serial number**
HMR code 21-004

# Study information

## Scientific Title
Phase 1 trial, HMR code: 21-004
The full scientific title will be published within 30 months after the end of the trial

## Study objectives
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## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Approved 29/06/2021, Health and Social Care Research Ethics Committee B (HSC REC B, Unit 4, Lissue Industrial Estate West, Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 28 95361400; recb@hscni.net), ref: 21/NI/0069
2. Approved 15/07/2021, MHRA (10 South Colonnade, Canary Wharf, London E14 4PU, UK; +44 20 3080 6000; info@mhra.gov.uk), ref: none provided
The HRA has approved deferral of publication of trial details.

## Primary study design
Interventional

## Study design
First-in-human safety tolerability and pharmacokinetics trial in up to 104 healthy men

## Study type(s)
Other

## Health condition(s) or problem(s) studied
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## 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)
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### Completion date
30/11/2022

## Eligibility

### Key inclusion criteria
Healthy human volunteer

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Male

### Key exclusion criteria
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### Date of first enrolment
09/08/2021

### Date of final enrolment
30/08/2022

## Locations

### Countries of recruitment
United Kingdom

England

**Study participating centre**
**Hammersmith Medicines Research Limited**
Cumberland Avenue
London
United Kingdom
NW10 7EW

# Sponsor information

**Organisation**
Gedeon Richter Plc

# Funder(s)

**Funder type**
Industry

**Funder Name**
Gedeon Richter Plc

# 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