

Phase 1 trial, HMR code: 21-004

Submission date 09/03/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/03/2022	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/03/2022	Condition category Not Specified	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

Dr Denisa Wilkes

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2021-001912-26

Integrated Research Application System (IRAS)

1003759

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Study information

Scientific Title

Phase 1 trial, HMR code: 21-004

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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.

Study design

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

Primary study design

Interventional

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