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

Phase 1 trial, HMR code: 21-004

Submission date 09/03/2022	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 24/03/2022	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 24/03/2022	**Condition category** Not Specified	[ ] Individual participant data [ ] 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
Hammersmith Medicines Research
Cumberland Avenue
London
United Kingdom
NW10 7EW
+44 20 8961 4130
rec@hmrlondon.com

Additional identifiers

EudraCT/CTIS number
2021-001912-26

IRAS number
1003759

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

IRAS 1003759, 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.

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

Primary study design
Interventional

Secondary study design
Part A – double-blind, placebo-controlled, parallel group; Part B – open-label, 2-way crossover assessment of the effect of food

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
No participant information sheet available

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 measure
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Secondary outcome measures
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Overall study start date
27/05/2021

Completion date
30/11/2022

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
Up to 104

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
England

United Kingdom

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

Sponsor information

Organisation
Gedeon Richter Plc

Sponsor details
Gyömrői út 19-21
Budapest
Hungary
H-1103
+36 1-431-4000
ra.ctarichter@richter.hu

Sponsor type
Industry

Funder(s)

Funder type

Industry

Funder Name
Gedeon Richter Plc

Results and Publications

Publication and dissemination plan
Trial information and summary results 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.

Intention to publish date
30/05/2025

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