ISRCTN10047421 https://doi.org/10.1186/ISRCTN10047421

Phase I trial HMR code: 23-007

Submission date 17/01/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/01/2024	**Overall study status** Deferred	
Last Edited 22/01/2024	**Condition category** Other	

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

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Additional identifiers

Integrated Research Application System (IRAS)
1008807

Protocol serial number
HMR code: 23-007

Study information

Scientific Title
Phase I trial HMR code: 23-007 [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
Ethics approval required

Ethics approval(s)
Approved 12/01/2024, South Central – Oxford A REC (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)207 1048171; oxforda.rec@hra.nhs.uk), ref: 23 /SC/0316

Primary study design
Interventional

Study design
First-in-human safety, pharmacokinetics, and pharmacodynamics trial in up to 176 healthy volunteers

Study type(s)
Other

Health condition(s) or problem(s) studied
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Interventions
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.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary 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.

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
25/07/2025

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
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Date of first enrolment
24/01/2024

Date of final enrolment
25/04/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
HMR
Cumberland Avenue
Park Royal
London
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NW10 7EW

Sponsor information

Organisation
Gedeon Richter (Hungary)

ROR
https://ror.org/0033rtn64

Funder(s)

Funder type
Industry

Funder Name
Gedeon Richter

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Hungary

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