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
Registration date 22/01/2024	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 22/01/2024	**Condition category** Other	[_] Individual participant data [_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1008807

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1008807 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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial; open label cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format

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

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

Pharmaceutical study type(s)
Other: 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.

Phase
Phase I

Drug/device/biological/vaccine name(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.

Primary outcome measure

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.

Secondary outcome measures
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.

Overall study start date
27/10/2023

Completion date
25/07/2025

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Up to 176

Key exclusion criteria
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.

Date of first enrolment
24/01/2024

Date of final enrolment
25/04/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
HMR
Cumberland Avenue
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Sponsor information

Organisation
Gedeon Richter (Hungary)

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Sponsor type
Industry

Website
https://www.richter.hu/en-US/Pages/default.aspx

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

Publication and dissemination plan
Full trial details 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 I study and the negligible benefit to the public of Phase I information. Results will be posted after the end of the Phase II trial.

Intention to publish date
25/01/2028

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