ISRCTN11493807 https://doi.org/10.1186/ISRCTN11493807

Phase I trial HMR code: 25-001

Submission date 09/05/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/05/2025	**Overall study status** Deferred	
Last Edited 31/07/2025	**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)
1011834

Protocol serial number
HMR code: 25-001, Sponsor code: KMI-001/BIO

Study information

Scientific Title
Phase I trial HMR code: 25-001 [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 04/06/2025, London - Harrow Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8154; Harrow.rec@hra.nhs.uk), ref: 25/LO/0225

Primary study design
Interventional

Study design
Phase I safety, pharmacokinetics and pharmacodynamics trial in up to 84 healthy participants

Study type(s)
Other

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
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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
06/07/2026

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
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Date of first enrolment
03/06/2025

Date of final enrolment
06/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Medicines Research (HMR)
Cumberland Avenue
Park Royal
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United Kingdom
NW10 7EW

Sponsor information

Organisation
Dr Falk Pharma GmbH

Funder(s)

Funder type
Industry

Funder Name
Dr Falk Pharma GmbH

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