

Phase I trial HMR code: 25-001

Submission date 09/05/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/05/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/07/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1011834

ClinicalTrials.gov (NCT)

Nil known

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

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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

Study design

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

Primary study design

Interventional

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)

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Key secondary outcome(s)

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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

London

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