Phase I trial HMR code: 25-001

Submission date	Recruitment status	[X] Prospectively registered
09/05/2025	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
16/05/2025	Deferred	Results
Last Edited	Condition category	Individual participant data
31/07/2025	Other	[X] 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

Dr Adeep Puri

Contact details

Hammersmith Medicines Research (HMR) Cumberland Avenue, Park Royal London United Kingdom NW10 7EW +44 (0)20 8961 4130 rec@hmrlondon.com

Type(s)

Public, Scientific

Contact name

Dr Ph1 Department

Contact details

Leinenweberstr. 5 Freiburg Germany

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

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

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

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)

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(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

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 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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes