Phase I trial HMR code: 25-001

Submission date 09/05/2025	Recruitment status Recruiting	[X] Prospectively registered
		☐ 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 yea

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

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Type(s)

Public, Scientific

Contact name

Dr Ph1 Department

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1011834

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format.

Health condition(s) or problem(s) studied

Healthy volunteers

Interventions

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Intervention Type

Drug

Pharmaceutical study type(s)

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Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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Overall study start date

01/04/2025

Completion date

06/07/2026

Eligibility

Key inclusion criteria

Healthy human volunteer

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

Up to 84

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

England

United Kingdom

Study participating centre

Hammersmith Medicines Research (HMR)

Cumberland Avenue Park Royal London United Kingdom NW10 7EW

Sponsor information

Organisation

Dr Falk Pharma GmbH

Sponsor details

Leinenweberstr. 5
Freiburg
Germany
79108
+49 (0)76115140
phase1@drfalkpharma.de

Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Dr Falk Pharma GmbH

Results and Publications

Publication and dissemination plan

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.

Intention to publish date

06/01/2029

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