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

Phase I trial HMR code: 25-001

Submission date 09/05/2025	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] 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

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

79108
+49 (0)76115140
phase1@drfalkpharma.de

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
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)
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Phase
Phase I

Drug/device/biological/vaccine name(s)
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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
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