ISRCTN55493273 https://doi.org/10.1186/ISRCTN55493273

Phase 1 Trial: EMP-012-1

Submission date 24/02/2025	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 26/02/2025	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 26/02/2025	**Condition category** Other	[ ] Individual participant data [X] Record updated in last year

Plain English summary of protocol
The Health Research Authority (HRA) has approved 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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1011107

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1011107/EMP-012-1

Study information

Scientific Title
Phase 1 Trial: EMP-012-1

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/02/2025, North East-York Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8079; York.rec@hra.nhs.uk), ref: 25/NE/0004

Study design
First-in-man safety pharmacokinetic and pharmacodynamics trial in 80 subjects including healthy volunteers and patients

Primary study design
Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied
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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 Health Research Authority (HRA) has approved 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 Health Research Authority (HRA) has approved 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
18/12/2026

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

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Date of first enrolment
24/02/2025

Date of final enrolment
20/05/2026

Locations

Countries of recruitment
United Kingdom

England

Australia

Study participating centre
Medicines Evaluation Unit Limited
The Langley Building
Southmoor Road
Wythenshawe
Manchester
United Kingdom
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Sponsor information

Organisation
Empirico Inc.

Funder(s)

Funder type
Industry

Funder Name
Empirico Inc.

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes