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

Phase 1 Trial: EMP-012-1

Submission date 24/02/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 26/02/2025	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 25/11/2026	**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

Integrated Research Application System (IRAS)
1011107

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

Primary study design
Interventional

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

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
22/10/2026

Eligibility

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

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
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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

IPD sharing plan summary

Data sharing statement to be made available at a later date