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

EudraCT/CTIS number
Nil known

IRAS number
1011107

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Safety

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacodynamic

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
18/12/2024

Completion date
18/12/2026

Eligibility

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

Age group
Adult

Sex
Both

Target number of participants
80

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
Australia

England

United Kingdom

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

Organisation
Empirico Inc.

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Empirico Inc.

Results and Publications

Publication and dissemination plan
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.

Intention to publish date
18/06/2029

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