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ReMEdi - Randomised controlled trial of the safety and efficacy of PHOE-01 in ME/CFS with digital monitoring

Submission date 23/05/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/05/2025	**Overall study status** Deferred	
Last Edited 31/03/2026	**Condition category** Nervous System Diseases	

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 by the end date of the deferral (24 Jan 2026)

Contact information

Type(s)
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Additional identifiers

Integrated Research Application System (IRAS)
1010633

Protocol serial number
PHOE2024-01

Study information

Scientific Title
ReMEdi - Randomised controlled trial of the safety and efficacy of PHOE-01 in ME/CFS with digital monitoring

Acronym
ReMEdi

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 22/01/2025, South Central - Oxford B Research Ethics Committee (Health Research Authority, 2 Redman Place, London, E20 1JQ, United Kingdom; +44 207 104 8134; oxfordb.rec@hra.nhs.uk), ref: 24/SC/0409

2. Approved 24/01/2025, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 20 3080 6000; info@mhra.gov.uk), ref: CTA 17683/0223/001-0001

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)
Efficacy, Safety, Treatment

Health condition(s) or problem(s) studied
Myalgic Encephalomyelitis/Chronic Fatigue Syndrome

Interventions
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Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
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Key secondary outcome(s)
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Completion date
22/03/2026

Eligibility

Key inclusion criteria
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Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
25

Key exclusion criteria
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Date of first enrolment
05/02/2025

Date of final enrolment
08/01/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lindus Health
Second Floor, Harlequin Building, 65 Southwark Street
London
England
SE1 0HR

Sponsor information

Organisation
Alfred E. Tiefenbacher (Germany)

ROR
https://ror.org/05cs0pa90

Funder(s)

Funder type
Industry

Funder Name
Alfred E. Tiefenbacher

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available