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

Submission date	Recruitment status	[ ] Prospectively registered
23/05/2025	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/05/2025	Deferred	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/07/2025	Nervous System Diseases	[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 by the end date of the deferral (24 Jan 2026)

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1010633

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment, Safety, Efficacy

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

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

Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Dose response

Phase
Phase II

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
01/03/2024

Completion date
31/12/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

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

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lindus Health
Second Floor, Harlequin Building, 65 Southwark Street

London
United Kingdom
SE1 0HR

Sponsor information

Organisation
Alfred E. Tiefenbacher (Germany)

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Sponsor type
Industry

Website
https://aet.eu/

ROR
https://ror.org/05cs0pa90

Funder(s)

Funder type
Industry

Funder Name
Alfred E. Tiefenbacher

Results and Publications

Publication and dissemination plan
Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this study. Results will be posted on or after the date of publication of full trial details.

Intention to publish date

31/12/2026

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 commercial sensitivity

IPD sharing plan summary

Not expected to be made available