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E-CLAD UK Long-term

Submission date
22/05/2026

Recruitment status
Recruiting

Registration date
04/08/2026

Overall study status
Ongoing

Last Edited
04/08/2026

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looks at the long term effects of a treatment called extracorporeal photopheresis (ECP) in people who have had a double lung transplant and later develop chronic lung allograft dysfunction. This condition means the body starts to reject the transplanted lungs over time. An earlier study followed people for 24 weeks, but it did not show the longer term impact of the treatment. This follow up study aims to understand how the treatment affects health, quality of life, and use of health services over a longer period of up to two years. It also looks at whether the treatment offers good value for money compared to standard care alone.

Who can participate?
Adults who took part in the earlier E-CLAD UK clinical trial can join this follow up study. They must have completed the original trial and be able to give written consent. Healthy volunteers cannot take part.

What does the study involve?
Participants will be asked to complete two short quality of life questionnaires at up to three time points over two years. Each questionnaire takes about ten minutes and can be completed online using a phone, tablet, or computer.
Information about participants' health, treatments, and use of NHS services will also be collected from their medical records at around 52 weeks and 104 weeks.
Some participants, up to 20 people, may be invited to take part in a telephone or video interview lasting about one hour. This will explore their experiences of treatment and care.

What are the possible benefits and risks of participating?
There may be no direct benefit to participants, but the study will help improve understanding of long term outcomes for people with this condition and may benefit future patients.
There are no known risks from taking part in this study, as it mainly involves questionnaires and review of medical records.

Where is the study run from?
Newcastle Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
July 2024 to December 2029.

Who is funding the study?
Therakos (UK)

Who is the main contact?
e-clad@newcastle.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
None - Trial Manager

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Additional identifiers

Integrated Research Application System (IRAS)
338850

Central Portfolio Management System (CPMS)
60828

Study information

Scientific Title
Extracorporeal photopheresis in the treatment of chronic lung allograft dysfunction: long-term follow-up study

Acronym
E-CLAD UK Long-term

Study objectives
The primary objective of the E-CLAD UK long-term follow-up study is to determine whether ECP therapy plus standard care is more cost-effective than standard care alone at managing lung function in patients with CLAD following double lung transplant.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/04/2024, West Midlands - South Birmingham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; no telephone number provided; southbirmingham.rec@hra.nhs.uk), ref: 24/WM/0075

Primary study design
Observational

Secondary study design
Longitudinal study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic lung allograft dysfunction

Interventions
The study is a follow on from the E-CLAD study. https://www.isrctn.com/ISRCTN10615985

E-CLAD UK Long-term is an observational study. Participants will be required to complete two different quality of life questionnaires at up to three different time points over a two-year period. The timepoints will depend on whether participants completed the 24-week visit in the E-CLAD UK trial. The questionnaires will be the same as those used in the original trial and should take no more than ten minutes to complete.

The first timepoint will coincide with the scheduled week-24 visit for the E-CLAD UK trial. Should participants reach this study visit in the original trial then they will be completed as part of the E-CLAD UK trial and will not be repeated for this study. Questionnaires will then be repeated at 52 weeks and 104 weeks after the start of participants involvement in the E-CLAD UK trial. Questionnaires will be set up to allow participants to complete remotely on a mobile phone, tablet, computer or laptop.

Consent will be obtained to allow the collection of additional information from participant's medical records. This will be information on their condition, any further treatments received and their usage of the NHS. This information will be collected by the research team at the participant's local hospital. This information will be collected at the 52- and 104-week timepoint.

Participants will also be invited to be interviewed as part of a qualitative sub-study. Up to 20 participants will take part in an interview about their long-term views on their medical treatment during the trial and subsequent post-trial care. Interviews will be conducted remotely and expected to last about an hour.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
UVADEX [Methoxsalen]

Primary outcome(s)
1. Incremental cost per quality-adjusted life year gained measured using Cost-effectiveness modelling using EQ-5D-5L responses for QALY estimation and health care usage data from E-CLAD UK clinical trial and E-CLAD UK Long-term at 52 weeks, 104 weeks post commencement

Key secondary outcome(s)
1. Rate of decline in lung function measured using Forced expiratory volume in 1 second and forced vital capacity obtained from routine clinical pulmonary function tests recorded in case report forms at 52 weeks, 104 weeks

2. Absolute change in lung function measured using Forced expiratory volume in 1 second and forced vital capacity obtained from routine clinical pulmonary function tests recorded in case report forms at 52 weeks, 104 weeks

3. Health care utilisation measured using Case report forms completed using data from routine clinical notes including medication changes, blood tests, chest X-rays and new interventions at 24 weeks, 52 weeks, 104 weeks

4. Health-related quality of life measured using EQ-5D-5L and SF-36 v2 Quality of Life Questionnaires at 24 weeks, 52 weeks, 104 weeks

5. Survival status measured using Review of patient medical records at 104 weeks

Completion date
31/12/2029

Eligibility

Key inclusion criteria
1. Consented and subsequently randomised to the E-CLAD UK clinical trial
2. Capacity to provide written informed consent to E-CLAD UK Long-term
3. Completed participation in the E-CLAD UK clinical trial

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Any participants that are consented to the E-CLAD UK clinical trial but during final eligibility checks are found to not meet eligibility requirements and are therefore not subsequently randomised to the E-CLAD UK clinical trial would not be eligible for E-CLAD UK Long-term
2. Lacking capacity to provide written informed consent to E-CLAD UK Long-term

Date of first enrolment
23/07/2024

Date of final enrolment
30/06/2029

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre
Royal Papworth Hospital NHS Foundation Trust
Papworth Road
Cambridge Biomedical Campus

Cambridge
England
CB2 0AY

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
England
SE1 7EH

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type

Industry

Funder Name
Therakos

Alternative Name(s)
Therakos, Inc., Therakos Photopheresis

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date