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Randomised controlled trial of dialysate cooling for preservation of cognitive function in haemodialysis

Submission date	Recruitment status	[ ] Prospectively registered
23/04/2026	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/05/2026	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/05/2026	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Thinking and memory problems affect working memory and people's abilities to remember and perform daily life tasks. Thinking and memory problems are common in people receiving haemodialysis. Haemodialysis can affect blood pressure and the brain blood supply, which may lead to worsening in thinking and memory abilities. There are currently no treatments to protect against thinking and memory problems in people receiving haemodialysis. Dialysate cooling is a method of reducing the temperature of the fluid used in the haemodialysis machine and has been shown to have positive effects on blood pressure in other studies. This study will explore whether dropping the temperature of dialysis fluid by 0.5 degrees (dialysate cooling) can preserve thinking and memory functions in people receiving haemodialysis.

Who can participate?
Patients over the age of 18 years who are receiving haemodialysis

What does the study involve?
The study involves participants undergoing their usual haemodialysis. Some participants will be randomly allocated to have dialysis at a cooler temperature (0.5 degrees lower than body temperature). At baseline and after 1 year, all participants will complete a number of questionnaires and cognitive assessments

What are the possible benefits and risks of participating?
Dialysate cooling is safe and no riskier than usual dialysis treatment. Some patients do report coldness or feeling cold during dialysis treatment.
This study will help us answer the question of whether dropping the temperature of the dialysis fluid by 0.5 degrees below the person's body temperature is the way to preserve thinking and memory functions in people receiving haemodialysis.

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

When is the study starting and how long is it expected to run for?
April 2026 to October 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Derby Clinical Trials Unit, uhdb.coolhdstudy@nhs.net

Contact information

Type(s)
Scientific

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Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
345755

Central Portfolio Management System (CPMS)
63214

National Institute for Health and Care Research (NIHR)
208855

Study information

Scientific Title
Randomised controlled trial of dialysate cooling for the preservation of cognitive function in haemodialysis patients (COOL HD)

Acronym
COOL HD

Study objectives
This study aims to answer the question of whether lowering the dialysis fluid temperature by 0.5 degrees below the person's body temperature leads to preservation of thinking and memory functions in people receiving Haemodialysis.

The study will measure secondary outcomes such quality of life, hospitalisation episodes and length of these hospital admissions, the degree of frailty and any adverse events related to cooling such as feeling cold and heart and stroke events.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/02/2026, Yorkshire & The Humber - Leeds East Research Ethics Committee (N/A, N/A, N/A, United Kingdom; N/A; leedseast.rec@hra.nhs.uk), ref: 26/YH/0023

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cognitive function in haemodialysis patients

Interventions
This is a randomised study, meaning participants are assigned by chance to one of two groups for 1 year:
1. Dialysis fluid is set at 37°C (normal body temperature)
2. Dialysis fluid is set at 0.5°C below the person's body temperature.

Participants will have two main study visits at the start of the study and 1 year later

At both visits, trained researchers will assess:
1. Thinking and memory (using simple tests)
2. Frailty (how physically vulnerable someone is)
3. Quality of life (how people feel day-to-day)

These assessments will be done before a dialysis session. At the start, researchers will also record:
1. Age, sex, ethnicity
2. Height, weight, blood pressure
3. Dialysis details and medical history
4. Current medications
5. Routine blood test results (already taken as part of normal care)

During the year dialysis temperature will be checked monthly; blood results, hospital admissions, and heart-related events will be reviewed every 3 months. Safety will be monitored throughout the study.

Intervention Type
Other

Primary outcome(s)
1. Working memory measured using the Letter Number Sequencing (LNS) test at 1 year after randomisation

Key secondary outcome(s)
1. Other cognitive domains: processing speed, inhibition, attention, perception and general cognition and memory measured using Digit symbol matching task, Flanker Test and Letter Number Sequence Task at baseline and 12 months
2. Clinical outcomes, namely, number and length of hospitalisation episodes and frailty score measured by the clinical frailty score at baseline and 12 months
3. Quality of life measured by the Short Form Health Survey Questionnaire (SF-36) at baseline and 12 months
4. Adverse events and serious adverse events related to intervention, cardiovascular events and cerebral ischaemic events recorded at baseline, 3, 6, 9 and 12 months

Completion date
31/10/2027

Eligibility

Key inclusion criteria
1. The participant is receiving maintenance in-centre haemodialysis
2. Over 18 years of age at time of consent
3. The participant is able and willing to provide written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Participants with confirmed diagnosis of dementia
2. Participants who lack capacity to consent
3. Participants having dialysis less than three times a week
4. Pregnant participants

Date of first enrolment
01/04/2026

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Derby and Burton NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road

Derby
England
DE22 3NE

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
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Study participating centre
University Hospitals of Leicester NHS Trust
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Sponsor information

Organisation
University Hospitals of Derby and Burton NHS Foundation Trust

ROR
https://ror.org/04w8sxm43

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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