

Optimizing fluid management to improve recovery time in patients treated with Hemodialysis: A stepped-wedge cluster randomized trial using the Recova® decision aid

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Registration date 28/10/2025	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/10/2025	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Haemodialysis (HD) is a life-saving treatment for people with severe kidney disease. It can be used while waiting for a kidney transplant, but for many people it becomes a lifelong treatment. Most patients need dialysis three times a week, for about four to five hours each time.

An important part of dialysis care is managing the amount of fluid in the body. If too much fluid is removed, patients can feel weak, dizzy or tired. If too little is removed, it can cause swelling or heart problems. Finding the right balance is therefore very important for both short- and long-term health.

Many patients also feel tired after dialysis. The time it takes to feel fully recovered after a session is called recovery time (RT), and this has a big impact on quality of life.

This study looks at a decision-support tool called Recova®, which helps healthcare staff manage patients' fluid balance. Recova® combines clinical assessments with a method called bioimpedance spectroscopy (BIS) to better understand how much fluid is in the body. The aim of the study is to find out whether using Recova® can improve fluid management and shorten recovery time after dialysis. The study followed patients for 12 weeks.

Who can participate?

Adults with chronic kidney disease who receive regular haemodialysis and need fluid removal as part of their treatment.

What does the study involve?

The Recova® tool was introduced in 10 dialysis clinics across Sweden. Healthcare professionals were trained to use it and to regularly check patients' symptoms and signs of fluid imbalance. Each patient was assessed every two weeks, for a total of six times over the 12-week study period.

The main things measured were: 1) Fluid balance, using bioimpedance spectroscopy (BIS) and 2)

Recovery time, using the question: “How long does it take you to feel recovered after dialysis?” A secondary measure was a volume status score, based on the Recova® assessment. Before and after the 12-week period, results were compared to see if there were any changes.

What are the possible benefits and risks of participating?

There are no direct or immediate benefits for patients who take part in this study. However, in the long term, the results may help improve dialysis care and lead to more personalised treatments for future patients.

Completing the questionnaires may also give participants a chance to reflect on their own health and care needs. Many people find it meaningful to take part in research that can increase knowledge and help improve care for others in the future.

Previous studies have shown that healthcare staff appreciate having tools like Recova® to help them regularly and systematically assess dialysis patients’ symptoms.

The study is based on safe and established treatment methods and does not involve any medical risks. The main potential risk relates to privacy, since some health information will be collected from medical records and from the Swedish Renal Registry (SNR). However, all patients included in the SNR have already given consent for their information to be used in research.

Patients who take part in the study will: Complete questionnaires about their health and quality of life (this takes about 20 minutes); Take part in a few simple physical tests during their regular dialysis sessions; Have two extra fluid measurement (bioimpedance test), which takes about 10 extra minutes.

Any discomfort from these activities is expected to be very small.

Where is the study run from?

The study is coordinated from Uppsala, Sweden, and involves 10 dialysis clinics across five Swedish regions.

When is the study starting and how long is it expected to run for?

The study started in August 2022, and data collection was completed in June 2024.

Who is funding the study?

- Uppsala University Hospital ALF grants and establishment funding
- CUWX Foundation
- The Swedish Kidney Foundation
- The Regional Research Council Mid-Sweden (RFR-981084)

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
FOU2022-00112

Study information

Scientific Title
Optimizing fluid management to improve recovery time in patients treated with Hemodialysis: A stepped-wedge cluster randomized trial using the Recova® decision aid

Acronym
Recova-Recovery

Study objectives
To evaluate if use of Recova® contributed improved fluid management assessed as changes in fluid status and self-reported time to recovery after dialysis.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 08/04/2022, Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, Uppsala, 750 02, Sweden; +46-10-475 08 00; registrator@etikprovning.se), ref: 2021-06796-01

Study design

Stepped-wedge cluster randomized study

Primary study design

Interventional

Study type(s)

Quality of life, Treatment

Health condition(s) or problem(s) studied

Chronic kidney disease treated with hemodialysis

Interventions

A stepped-wedge cluster randomized trial was conducted across 10 hemodialysis (HD) clinics in five Swedish regions; each clinic was considered a cluster.

Recognition and Correction of Volume Alterations (Recova®), a fluid management decision aid combining clinical assessments with bioimpedance spectroscopy (BIS), was implemented at each clinic. A protocol for symptom assessment was provided for each study participant, and the healthcare professionals were trained to assess and respond to the patients' signs and symptoms every 14 days, on six occasions. The intervention period was 12 weeks, and the effect was assessed with pre- and post-intervention measurements in each study participant.

The clinics were included and assigned to the intervention consecutively, based on their availability.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Fluid status and recovery time were measured using bioimpedance spectroscopy and patients answering, "How long does it take you to recover from dialysis?" at baseline and after 12 weeks exposure to the intervention.

Key secondary outcome(s)

Volume status scores were measured using Recova® every second week during the 12 weeks intervention period i.e. at six occasions.

Completion date

02/01/2024

Eligibility

Key inclusion criteria

Patients over 18 years of age who had been treated with hemodialysis for more than three months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

129

Key exclusion criteria

1. Patients with critical illness
2. Expected survival less than 6 months
3. Inability to provide informed consent - due to language or cognitive insufficiency
4. Home-HD treatment
5. Pacemaker
6. Did not have a documented need for ultrafiltration

Date of first enrolment

24/08/2022

Date of final enrolment

02/01/2024

Locations

Countries of recruitment

Sweden

Study participating centre

Dialysis unit Karlskoga Hospital

Karlskoga lasarett

Karlskoga

Sweden

691 81

Study participating centre

Dialysis unit Mora

Medicin och geriatrik, Mora lasarett
Mora
Sweden
792 85

Study participating centre

Hemodialysmottagningen Universitetssjukhuset Örebro

Verksamhetsområde medicin, Universitetssjukhuset Örebro,
Örebro
Sweden
701 85

Study participating centre

Dialysis unit Gävle

Gävle sjukhus, Dialysmottagning, Lasarettsvägen 1
Gävle
Sweden
801 87

Study participating centre

Dialysis unit Bollnäs

Bollnäs sjukhus, Dialysmottagning, Sjukhusvägen 81
Bollnäs
Sweden
821 81

Study participating centre

Dagvård Dialys Södersjukhuset, Karolinska Universitetssjukhuset

Sjukhusbacken 14, Plan -2, hiss S
STOCKHOLM
Sweden
118 83

Study participating centre

Dialysis unit Falun and Ludvika

Medicin Falun, Dialysmottagning Falun, Falu lasarett
Falun
Sweden
791 82

Study participating centre

Dialysis unit, Njurmedicinska kliniken US
Njurmedicinska kliniken, Universitetssjukhuset
Linköping
Sweden
581 85

Study participating centre

Dialysenheten LiM, Njurmedicinska kliniken US
Dialysenheten, Lasarettet,
Motala
Sweden
591 85

Sponsor information

Organisation

Uppsala University

ROR

<https://ror.org/048a87296>

Funder(s)

Funder type

University/education

Funder Name

Akademiska Sjukhuset

Alternative Name(s)

Uppsala University Hospital

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Sweden

Funder Name

The Foundation for the Association of Kidney Patients in the CUWX Counties

Funder Name

Njurfonden

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Sweden

Funder Name

Regional Research Council Mid-Sweden

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will not be publicly available due to their containing information that could compromise the privacy of research participants - but are available from the corresponding author on reasonable request. The study data will be stored in a separate database requiring authentication for access. All data will be stored for 10 years after the study is completed and then archived at Uppsala University Hospital in accordance with current archive legislation.

IPD sharing plan summary

Available on request