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The implementation of a new form of dialysis at the dialysis department of the Albert Schweitzer Hospital, Dordrecht, the Netherlands

Submission date 09/12/2021	**Recruitment status** Stopped	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/12/2021	**Overall study status** Stopped	
Last Edited 13/08/2024	**Condition category** Other	

Plain English summary of protocol

Current plain English summary as of 28/04/2022:
Background and study aims
In hemodialysis, blood is treated in an extracorporeal system. In the dialyzer, diffusion against the dialysis fluid occurs. In hemodiafiltration, an extra amount of substitution fluid is administered as well in order to achieve higher ultrafiltration. This enhances the clearance of the so-called middle molecules. It is to be expected that changes in hemodialysis and hemodiafiltration practice will be implemented in the foreseeable future.

This study will investigate whether and how a new way of hemodialysis and hemodiafiltration differs from the earlier form in terms of effectiveness with regard to side effects and laboratory values. This will be achieved by systematic analysis of parameters collected routinely during the dialysis treatment.

Who can participate?
Patients in the Dialysis Department of the Albert Schweitzer Hospital

What does the study involve?
The study will use data from the treatment or laboratory values that are used in regular treatment extracted from electronic patient files.

What are the possible benefits and risks of participating?
This study will systematically evaluate the new treatment. It will involve extra monitoring besides the treatment as supervised by the individual physician. There are no risks or dangers to the patient.

Where is the study run from?
Albert Schweitzer Hospital (Netherlands)

When is the study starting and how long is it expected to run for?
September 2021 to January 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr M.R Korte
2. Dr G.M.T. de Jong, g.m.t.de.jong@planet.nl

Previous plain English summary:
Background and study aims
Hemodialysis or hemodiafiltration is a process of purifying the blood of a person whose kidneys are not working normally. It can only be performed when the blood inside the dialyzer is anticoagulated (to prevent blood clots). Heparin achieves this at the cost of anticoagulation in the patient as well. In simplified regional citrate anticoagulation (SRCA), the anticoagulation is limited to the dialyzer. The nephrologists of the Albert Schweitzer hospital have decided to change hemodialysis and hemodiafiltration treatment from heparin to SRCA. The study will observe the effectiveness and complications in both periods.

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Patients in the Dialysis Department of the Albert Schweitzer Hospital

What does the study involve?
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Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1

Study information

Scientific Title
An observational study into quality of hemodialysis in the Dialysis Department of the Albert Schweitzer Hospital, the Netherlands

Acronym
KwalitASz

Study objectives
Current study hypothesis as of 28/04/2022:
Implementation of a new standard method of hemodialysis/-diafiltration (HD(F)) can be done with the protocol used and is not inferior to the previous practice of (HD(F)).

Previous study hypothesis:
Implementation of Simplified Regional Citrate Anticoagulation hemodialysis/-diafiltration (SRCA HD(F)) can be done with the current protocol and is not inferior to low molecular heparin hemodialysis/-diafiltration (LMWH HD(F)) as done until then.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 29/04/2022:
Approved 06/12/2021, amendment approved 14/04/2022, Medical Ethics Committee Erasmus MC, Rotterdam (PO Box 2040, 3000 CA Rotterdam, The Netherlands; +31 (0)10 7033625; metc@erasmusmc.nl), ref: MEC-2021-0870

Previous ethics approval:
Approved 06/12/2021, Medical Ethics Committee Erasmus MC, Rotterdam (PO Box 2040, 3000 CA Rotterdam, The Netherlands; +31 (0)10 7033625; metc@erasmusmc.nl), ref: MEC-2021-0870

Study design
Before-and-after observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hemodialysis

Interventions
Current intervention as of 03/05/2022:
The nephrologists of the Albert Schweitzer Hospital have decided to change standard haemodialysis treatment in the near future. The study will observe standard parameters in both periods. The study will be done in the Dialysis Dept of the ASz, a STZ-hospital, at Dordrecht. The Dialysis Dept is situated at the location Dordwijk.

The current study is a before-after observational study. Every patient is their own control. After a period with the earlier method of HD(F), the patient will be treated with the new method. Every patient receives HD(F) three times per week. The presiding nephrologist will decide on the form of HD(F) which is prescribed. Patients will be treated with the earlier and the new method for at least 12 HD sessions each.

Laboratory measurements are performed according to the protocol in force. No additional blood samples or tests are done. Bone densitometry is done according to the treatment protocol in force.

Before and at the end of HD(F) the nurses record parameters in the EPD Diamant according to the protocol in force. This implies clock time, weight, blood pressure, pulse, ionic dialysance, ultrafiltration rate, arterial and venous machine pressure, transmembrane pressure (TMP),

before/ at the start and the end of HD(F). After HD(F) as well: blood flow achieved, total ultrafiltration, the total amount of blood being treated, a score of clotting in venous chamber and in dialyzer as well as whether there was a change from HD to HDF or addition of citrate infusion during the session. Dialysis parameters are available in the dialysis machine and don't require extra tests of the patient.

For parameters that are measured only once per session, the values will be compared between the two periods. For parameters that are measured only twice per session, absolute values, as well as their difference, will be compared between the two periods. With regard to bone densitometry, the score will be analysed as to whether and how much this has diminished in comparison to the earlier method.

Statistical analysis will be done with linear mixed models to correct for repeated measurements. The dependent variables in the model are the observed parameters. For parameters that are measured once per session, independent variables are the day of the week and the method of treatment (earlier vs. new) with a random intercept to correct for correlation within the individual. For parameters that are measured twice per session, independent variables are day of the week, the method of treatment (earlier vs. new), the timing of observation (before or after), and the interaction between time of observation and method of treatment. With these models, random intercepts of the patient and of method of treatment are used to correct for correlations between repeated measurements. Results are reported with estimated marginal means (i.e. the predicted value, corrected for the effects of the covariables) and their 95% confidence interval. If necessary, a Bonferroni correction will be applied. For the comparison of the bone densitometry, a non-parametric, paired t-test (Wilcoxon) will be used. A $p < 0,05$, double-sided, will be regarded as significant.

Previous intervention as of 28/04/2022:
The nephrologists of the Albert Schweitzer Hospital have decided to change standard hemodialysis treatment in the near future. The study will observe standard parameters in both periods

Previous intervention:
The nephrologists of the Albert Schweitzer Hospital have decided to change hemodialysis treatment from LMWH HD(F) to SRCA HD(F). The study will observe standard parameters in both periods.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome measure as of 03/05/2022:
Quality of the subsequent treatments measured using the statistical difference between the following parameters:
1. Values of laboratory tests including bone densitometry which are taken routinely according to the protocol in force before and after dialysis treatment
2. Dialysis readings that are taken routinely and are available in the dialysis machine including clock time, weight, blood pressure, pulse rate, dialysance clearance, ultrafiltration rate, arterial and venous pressure of the dialysis machine, and transmembrane pressure before and after each dialysis session; and blood flow rate, ultrafiltration achieved, and clotting in the dialyzer and venous chamber after rinsing with 300 ml NaCl 0,9% solution at the end of each dialysis session. Red colouring is scored by visual inspection by the nurse. Scoring is as follows: 0 no red fibers, 1

is less than 10% of fibers are red, 2 is more than 10% but less than 50% of fibers are red, 3 is more than 50% of fibers are red.
3. Dose of relevant medications used (relevant medication includes all medication with an effect on Ca- and Mg-balance, anticoagulation, erythropoietin, and iron suppletion) extracted from the hospital information system (HiX) by the Company Information Centre (BIC) before and after dialysis treatment
4. Number of blood transfusions given measured using details of blood transfusions which are registered in the hospital system Diamant at the time of transfusion

Current primary outcome measure as of 28/04/2022:
The quality of the subsequent treatments measured using the statistical difference between following parameters before, during and after dialysis:
1. Values of laboratory tests which are taken routinely
2. Dialysis readings that are taken routinely like clock time, weight, blood pressure, pulse rate, dialysance clearance, ultrafiltration rate, arterial and venous pressure of the dialysis machine, transmembrane pressure, blood flow rate, ultrafiltration achieved, BVAS of clots in the dialyzer and venous chamber
3. Dose of medications used

Previous primary outcome measure:
The quality of the subsequent treatments measured using the following parameters before, during and after dialysis:
1. Values of laboratory tests which are taken routinely
2. Dialysis readings that are taken routinely like clock time, weight, blood pressure, pulse rate, dialysance clearance, ultrafiltration rate, arterial and venous pressure of the dialysis machine, transmembrane pressure, blood flow rate, ultrafiltration achieved, BVAS of clots in the dialyzer and venous chamber
3. Dose of medications used relevant to clotting and calcium and phosphate homeostasis

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/01/2025

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
HD(F) patients at the Dialysis Department of the Albert Schweitzer Hospital, Dordrecht, The Netherlands

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
31/01/2024

Date of final enrolment
31/08/2024

Locations

Countries of recruitment
Netherlands

Study participating centre
Albert Schweitzer Hospital
Dialysis Department
Albert Schweitzerplaats 25
Dordrecht
Netherlands
3300 AK

Sponsor information

Organisation
Albert Schweitzer Ziekenhuis

ROR
https://ror.org/00e8ykd54

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available and will be held in the hospital computer system.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Dutch language	26/02/2022	28/04/2022	No	Yes
Participant information sheet	Participant information sheet version 1	11/11/2025	11/11/2025	No	Yes
Protocol file		26/11/2021	09/12/2021	No	No