

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/12/2021	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/08/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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.

Who can participate?
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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Before-and-after study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See addition file for information sheet in Dutch

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 measure

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

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/09/2021

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

Age group

Adult

Sex

Both

Target number of participants

100

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

Sponsor details

Albert Schweitzerplaats 25
Dordrecht
Netherlands
3300 AK
+31 (0)786541111
g.m.t.de.jong@planet.nl

Sponsor type

Hospital/treatment centre

Website

<https://www.asz.nl/>

ROR

<https://ror.org/00e8ykd54>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in nephrological journal, posters and oral presentations.

Intention to publish date

01/09/2025

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?
Protocol file	version 1	26/11/2021	09/12/2021	No	No
Participant information sheet	Dutch language	26/02/2022	28/04/2022	No	Yes

