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Comparison of the efficacy of two dialysis filters in removing larger molecules that accumulate in acute renal failure

Submission date
06/03/2012

Recruitment status
No longer recruiting

Registration date
01/05/2012

Overall study status
Completed

Last Edited
19/09/2014

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Dialysis removes substances from the blood to avoid uremia - a syndrome that intoxicates the patient by the accumulation of compounds that are usually excreted in the urine. There are more than 4000 of such substances but we currently measure only a few of them. Special filters in dialysis machines that allow those substances to be removed from the blood to the dialysate, the water that is used to wash the blood. These dialysis membranes usually only allow small substances to travel from the blood of the patient to the dialysate, such as urea, sodium, potassium and phosphorus. Bigger molecules can only be removed from the blood by dialysis membranes with a larger pore size. Hence, there might be a disadvantage in using large pores as the patient would lose important proteins like albumin. The aim of our study was to compare two dialyzers (the AV 1000S and the EMiC2) in their ability to eliminate small and bigger molecules. Both dialyzers are equal in membrane surface area and membrane material, but differ in their membrane pore size. The EMiC2 dialyzer has a larger pore size than the AV 1000S. We further aimed to investigate whether the dialyzer with the larger pore size would leak albumin.

Who can participate?
Every critically ill patient over the age of 18 with acute kidney injury undergoing extended dialysis with the GENIUS 90 system.

What does the study involve?
Every patient received two consecutive extended dialysis sessions starting in a random order with either the EMiC2 or the Ultraflux AV 1000S filter, followed by a treatment with the other dialyser. Levels of the molecules beta2-microglobulin, cystatin c, albumin, creatinine and urea were measured before and after 0.5, 5.0 and 10 hours of dialysis.

What are the possible benefits and risks of participating?
Dialysis with highly permeable membranes could lead to a mild protein loss which in itself does not present an increased medical risk. We monitored every patients nutritional status carefully and tailored the individual nutrition to the patients need. There might be a benefit of removing

larger substances from the blood of critically ill patients but the potential effect, if existent, will not be of clinical importance for the individual patient.

Where is the study run from?
The intensive care units of the Hannover Medical School (Germany).

When is the study starting and how long is it expected to run for?
Patients were enrolled between May 2009 and May 2012.

Who is funding the study?
Investigator-initiated trial.

Who is the main contact?
Jan T Kielstein
Kielstein@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Prof Jan T Kielstein

Contact details
Department of Nephrology and Hypertension
Medical School Hannover
Carl-Neuberg-Str. 1
Hannover
Germany
30625

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Hannover Medical School, Germany, protocol # 5307

Study information

Scientific Title
Comparison of middle molecule clearance and removal between a new high cut-off dialyzer to an established dialyzer - a clinical cross-over comparison in extended dialysis

Study objectives

We aimed to evaluate the efficiency of a new dialyzer comprised of a new polysulfone membrane and a bigger pore size in regard to its ability to eliminate beta-2 microglobulin (molecular weight 11.8 kDa), an excellent surrogate for middle molecules as well as its properties in terms of albumin (molecular weight 65 kDa) loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hannover Medical School, Germany, 27/04/2009, ref: 5307

Study design
Randomized cross-over comparison

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute kidney injury, renal replacement therapy

Interventions
In this prospective randomized cross-over trial every participating patient received two consecutive extended dialysis sessions starting in random order either with the EMiC2 or the Ultraflux AV 1000S dialyser followed by a treatment with the other dialyser. The duration of treatment for each patient was two days.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Dialyser clarance of middle molecules
2. Total amount of middle molecules in the combined spent dialysate and ultrafiltrate dialyzer clearance measured 30 min after start of treatment for the quantified substances according to equation 1 using the patients hematocrit level (Hct) at the time of clearance sampling.
Eq. 1: Kplasma = QB x (1 Hct/100) x ((Cart Cven)/Cart)

3. Reduction ratio (RR) determined for beta2-microglobulin, creatinine, cystatin c and urea. Therefore, blood samples will be collected right before the start (Cpre) as well as at the end (Cpost) of the treatment. Calculations of RR executed according to equation 2.
Eq. 2: RR = (Cpost Cpre)/Cpre x 100
Samples of the total spent dialysate will be drawn at the end of the treatment.

Secondary outcome measures
Albumin loss
Total loss of albumin by adding the albumin values in the total spent dialysate and ultrafiltrate. For concentrations below the detection limit of 1.1 mg/dl, an albumin concentration of 1.1 mg/dl was assumed.
Eq. 3: Alb = Calb(dialysate) x Vdialysate + Calb(ultrafiltrate) x Vultrafiltrate

Overall study start date
01/05/2012

Completion date
01/05/2012

Eligibility

Key inclusion criteria
1. Males and females
2. Aged > 18 years
3. Patients in the intensive care unit suffering from acute kidney injury [stage Acute Kidney Injury Network (AKIN) III], i.e. need for renal replacement therapy
4. Treatment using the 90 L GENIUS batch dialysis system
5. Signed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
11

Key exclusion criteria
1. Pregnant and nursing patients
2. Patients participating in a different study (other than observational)
3. All conditions deemed to justify exclusion by the recruiting physician

Date of first enrolment

01/05/2012

Date of final enrolment
01/05/2012

Locations

Countries of recruitment
Germany

Study participating centre
Department of Nephrology and Hypertension
Hannover
Germany
30625

Sponsor information

Organisation
Medical School Hannover (Germany)

Sponsor details
c/o Prof Jan T Kielstein
Department of Nephrology and Hypertension
Carl-Neuberg-Str. 1
Hannover
Germany
30625

Sponsor type
University/education

Website
http://www.mh-hannover.de

ROR
https://ror.org/00f2yqf98

Funder(s)

Funder type
Industry

Funder Name
Fresenius Medical Care (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration