ISRCTN33774458 https://doi.org/10.1186/ISRCTN33774458

Mortality and recovery of renal function in acute kidney injury patients treated with extended dialysis

Submission date
25/03/2014

Recruitment status
No longer recruiting

Registration date
16/04/2014

Overall study status
Completed

Last Edited
07/09/2018

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In critically ill patients with kidney failure (acute kidney injury), high death rates remain an unresolved problem, despite technological advancements in life-supporting treatment. Extended daily dialysis is an alternative therapy. We are carrying out a study to compare the death rate and recovery of kidney function in critical ill patients undergoing dialysis. Our goal is to find out if the dialysis sessions lasting 10 hours decrease the death rate and speed up recovery of the kidney function compared to sessions lasting 6 hours.

Who can participate?
Adult patients, with acute kidney injury, admitted to the intensive care unit of the participating hospital.

What does the study involve?
Patients are randomly allocated to one of two groups: Group 1 patients undergo dialysis lasting 6 hours and Group 2 patients undergo dialysis lasting 10 hours.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit and risk to those taking part.

Where is the study run from?
São Paulo State University UNESP Botucatu (Brazil).

When is study starting and how long is it expected to run for?
The recruitment started in January 2012 and is expected to end by January 2016.

Who is funding the study?
Sao Paulo Research Foundation, Brazil.

Who is the main contact?
Bianca Ballarin Albino, bibialbino@uol.com.br
Daniela Ponce, dponce@fmb.unesp.br

Contact information

Type(s)
Scientific

Contact name
Miss Bianca Ballarin Albino

Contact details
Emilio Garcia
275 Jardim Bom Pastor
Botucatu
Brazil
18603440

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Mortality and recovery of renal function in acute kidney injury patients treated with extended daily dialysis: is the duration of therapy important?

Study objectives
We hypothesized that the dialysis sessions lasting 10 hours cause less mortality and faster recovery of renal function than sessions lasting 6 hours.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee, 03/10/2011, ref. 446/2011

Study design
Prospective single-centre randomised clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute kidney injury

Interventions
The indications for dialysis are uraemic symptoms, blood urea nitrogen (BUN) level >100 mg/dl (azotaemia), volume overload, electrolyte imbalance (potassium > 6 mEq/l after clinical treatment), or acid-base refractory disturbances (bicarbonate <10 mEq/l after reposition). A patient was considered for enrolment if the judgment of the treating nephrologists was that he or she required dialysis and the mean arterial blood pressure (BP) was higher than 80 mmHg, with a noradrenaline dose lower than 0.7 ug/kg/min in the 8 hours preceding randomisation.

Patients were divided into two groups randomly, according to prescribed treatment time:
Group 1 (G1): patients undergoing EDD sessions lasting 6 hours
Group 2 (G2): patients undergoing EDD sessions lasting 10 hours

Dialysis was interrupted when there was partial renal function recovery (dialysis-independent), defined as restoration of urine output higher than 1000 ml/24 h associated with a progressive fall in serum values for creatinine (<4 mg/100 ml) and BUN (<50 mg/dl), a need to change dialysis method because of infectious, mechanical or haemodynamic complications, more than 30 days of follow-up, or death.

The EDD session last 6 or 10 hours according to randomisation and, for practical reasons, it was decided that EDD would be carried out 6 days a week (MondaySaturday). Dialysis nurses and dialysis technical nursing are responsible for EDD and operated the dialysis machines throughout the treatment. A double lumen catheter for central venous access (jugular, subclavian or femoral vein, depending on the ease of access) was inserted blindly at the bedside by nephrologists, under local anaesthesia. An HD machine with volumetric control (Fresenius 4008F or Gambro K200) and cellulose acetate dialysers (CA 150 or 170 with surface areas of 1.2 and 1.5 m2, respectively) are used for sessions of 6 and 10 hours, respectively. Blood flow is 200 ml/min and dialysate flow is 300 ml/min. Anticoagulation was achieved with unfractionated heparin (usually a 1000 U bolus followed by 500 U/h) or saline flushes of 100 ml given every 30 min if anticoagulation was contraindicated. If EDD was interrupted for procedures, it was restarted later, attempting to complete 6 or 10 h of treatment. UF is prescribed during dialysis treatment as per the daily requirements. UF is performed at 300 ml/h to 500 ml/h and adjusted according to the alteration in haemodynamic parameters and fluid status of individual patients.

Bicarbonate (26 to 35 mEq/l), potassium (2 or 3 mEq/l), and sodium dialysate concentrations (142 148 mEq/l) are adjusted according to individual requirements. Dialysate temperature is low (35.5° C) to prevent hypotension.
Treatment duration, episodes of filter clotting and replacement, vasoactive drug dose, and UF rate are recorded at the end of each session. Post-treatment BUN levels are measured by the slow flow method (with blood pump speed reduced to 50 ml/min). Blood samples are obtained from the arterial sampling port before the blood reached the dialyser. HD adequacy is determined by using urea kinetic modelling based on Kt/V. The delivered dose is determined by the single-pool Kt/V value, corrected for actual UF but not for the reappearance of urea nitrogen. Blood urea nitrogen, arterial blood pH, serum levels of bicarbonate, potassium and phosphate, urine output and fluid balance are recorded daily. Other clinical data are collected: sex, age, the presence of comorbidities (diabetes, chronic kidney disease and hypertension), primary diagnosis, the etiology of sepsis, prognostic score specific for AKI (ATN-ISS), SOFA, vasoactive drug dose before and after therapy, sessions numbers, the filter used, blood and dialysate flows, and actual UF.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. During the procedures, BP monitoring is performed every 30 min. Hypotension is defined as a single systolic BP of less than 90 mm Hg or a mean arterial pressure (MAP) of less than 60 mm Hg. To treat a hypotension episode during EDD, protocols are applied involving the infusion of saline, discontinuation of UF, and an increased dose of vasoactive drugs, according to the clinical condition and fluid status of the patient. If, despite the measures above, haemodynamic instability persisted, posing risks to the patient, the therapy are discontinued.
2. Filter clotting is diagnosed as the presence of blood clots in the circuit, composed of dialyser and lines, which prevented the continuation of therapy

Key secondary outcome(s))
Hypokalaemia and hypophosphataemia are considered post-dialysis complications, characterised by serum levels below 3.5 mEq/l and 3.5 mg/dl, respectively

Completion date
01/01/2016

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Patients with AKI associated with sepsis
3. Patients on an noradrenaline dose ranging from 0.3 to 0.7 ug/kg/min

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Severe chronic kidney disease (baseline creatinine higher than 4 mg/dL)
2. Previous chronic dialysis
3. Kidney transplantation
4. Noradrenaline using a dose higher than 0.7 mg/kg/min

Date of first enrolment
01/01/2012

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
Brazil

Study participating centre
Emilio Garcia
Botucatu
Brazil
18603440

Sponsor information

Organisation
Sao Paulo Research Foundation (FAPESP) (Brazil)

ROR
https://ror.org/02ddkpn78

Funder(s)

Funder type
Government

Funder Name
Fundação de Amparo à Pesquisa do Estado de São Paulo, 2011/19419-6

Alternative Name(s)
A Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP), São Paulo Research Foundation, State of São Paulo Research Foundation, Foundation for Research Support of the State of São Paulo, FAPESP

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Brazil

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/08/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes