

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

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Registration date 16/04/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/09/2018	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 (Monday-Saturday). 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 to 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 measure

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

Secondary outcome measures

Hypokalaemia and hypophosphataemia are considered post-dialysis complications, characterised by serum levels below 3.5 mEq/l and 3.5 mg/dl, respectively

Overall study start date

01/01/2012

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

170

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

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Sponsor information

Organisation

Sao Paulo Research Foundation (FAPESP) (Brazil)

Sponsor details

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Sponsor type
Government

Website
<http://www.fapesp.br/>

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)
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
Local government

Location
Brazil

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

Study outputs

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