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Different prescribed doses of high volume peritoneal dialysis and outcome of patients with acute kidney injury

Submission date	Recruitment status	[_] Prospectively registered
08/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/05/2010	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Different prescribed doses of high volume peritoneal dialysis and outcome of patients with acute kidney injury: a randomised controlled trial

Study objectives
Patients with acute kidney injury (AKI) treated with higher intensity of Peritoenal Dialysis (PD) presented lower mortality rate and better metabolic control.

Further reading:
Gabriel DP, Nascimento GVR, Caramori JT et al. Peritoneal dialysis in acute renal failure. Ren Fail 28: 451456. 2006 (Review)
http://www.ncbi.nlm.nih.gov/pubmed/16928612

Ethics approval required
Old ethics approval format

Ethics approval(s)
The local research ethics committee (Comitê de Ética em Pesquisa) approved on the 14th of September 2004 (ref: FMB 2004,112)

Study design
Randomised active controlled parallel group 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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute Kidney Injury

Interventions
We randomly assigned critically ill patients with AKI to receive higher or lower intensity PD therapy. A PD session was defined as 24 h of dialysis with sessions performed 7 days per week. Peritoneal access was established by percutaneous placement of a flexible catheter (Tenckhoff) by a nephrologist. The patients in both groups were treated with continuous and automated. Prescribed and delivered PD dose was determined by the formula urea Kt/V (18) as proposed by Gabriel et al (1,2). The prescribed Kt/V value was 0.8 per session for the higher intensity group or 0.5 per session for the lower intensity group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Death within 30 days

Secondary outcome measures
1. Recovery of kidney function within 30 days
2. Metabolic control

Overall study start date
01/01/2005

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. Adults with Acute Kidney Injury (AKI) according to Acute Kidney Injury Network (AKIN) criteria
2. Clinical diagnosis of severe acute tubular necrosis (ATN) caused by a recent ischemic or nephrotoxic injury. Severe ATN was defined as a history of prolonged and profound hypotension, severe nephrotoxic drugs overdose, or excess endogenous nephrotoxic pigments (hemoglobinuria, myoglobinuria). Diagnosis was based on clinical history, results of physical examination, relevant blood tests, and urinalysis (microscopical examination of urinary sediment), a fractional excretion of sodium that exceeded 1% and the findings on renal ultrasonography.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Under 18 years of age
2. Functional azotemia
3. Urinary tract obstruction
4. Acute interstitial nephritis
5. Rapidly progressive glomerulonephritis
6. History of chronic renal insufficiency (serum creatinine 43mg per 100 ml)

7. Renal transplantation
8. Pregnancy
9. Severe hypercatabolism according to Scherier criteria
10. Absolute contraindication for PD were recent abdominal surgery (less than one month)
11. Multiple abdominal surgeries (more than three)
12. Patients submitted to less than one session of high volume PD (HVPD), defined as 24 h.

Date of first enrolment
01/01/2005

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Brazil

Study participating centre
Distrito de Rubiao Junior (without number)
Botucatu
Brazil
18600000

Sponsor information

Organisation
São Paulo State University (Universidade Estadual Paulista [UNESP]) (Brazil)

Sponsor details
Distrito de Rubião Junior (without number)
Botucatu
Brazil
18600000

Sponsor type
University/education

ROR
https://ror.org/00987cb86

Funder(s)

Funder type
University/education

Funder Name
São Paulo State University (Universidade Estadual Paulista [UNESP]) (Brazil) - Departmental funding

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	01/05/2007		Yes	No
Results article	results	01/04/2008		Yes	No