

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

Submission date
08/05/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
20/05/2010

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
20/05/2010

Condition category
Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

Distrito de Rubiao Junior (without number)
Botucatu
Brazil
18600000

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 Peritoneal 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