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24-hour electrocardiogram profiles during acetate-free biofiltration with constant and potassium-profiled dialysate

Submission date 16/06/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/07/2006	**Overall study status** Completed	
Last Edited 08/09/2008	**Condition category** Circulatory System	

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

Study objectives
The aim of the study is to evaluate the efficacy of acetate-free biofiltration (AFB) potassium-profiled dialysis in the reduction of the number of cardiac arrhythmias during treatment, compared to constant potassium AFB.

One of the most important electrolyte disorders of uremia is the increase in serum potassium levels. A clinical consequence of hyperkalaemia is hyperpolarisation block of neuromuscular cells, which starts with asthaenia, muscular pain and constipation. The most worrying clinical outcome is at cardiac level which can induce severe hypokinetic arrhythmias up to total atrio-ventricular block bundle. Severe hyperkalaemia leads to a potassium transfer, mediated by sodium/potassium adenosine triphosphatase (Na/K-ATP-ase) pump, towards the intracellular space, thus increasing the concentration at this site. The task of dialysis treatment is to remove the extra amount of potassium in the interdialytic period due to the exogenous intake induced by vegetables, fruits, and their juices. The amount of potassium removed by dialysis is related to the concentration gradient between the serum potassium level and the potassium content of the dialysis bath. Very low concentration in the bath can remove large amounts of potassium from the body but against that of an altered concentration gradient between intra- and extra-cellular space with the appearance of electrical instability of cellular membrane, in particular, in pacemaker heart cells. Hyperkinetic arrhythmias have been seen which can prove to be harmful for the cardiac function. This phenomenon is even more evident in the presence of cardiac co-morbid conditions such as dilated hypertrophic cardiomyopathy.

The need to join adequate potassium removal with the risk of cardiac failure suggests use of sequential removal of potassium during dialysis.

The acetate-free biofiltration potassium profiled (AFBK) is a dialytic therapy which has such a safe feature.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study received appropriate ethics committee approval on 19/09/2002 by the Ethical Committee of Policlinico Sant' Orsola-Malpighi, (Comitato Etico del Policlinico Sant'Orsola-Malpighi), reference number: 1264/2002

Study design
Multicenter, randomised, crossover, single-blind scheme with two arms.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiac arrhythmia

Interventions
Dialysis with AFB potassium-profiled (AFBK) dialysis versus constant constant AFB.
In both AFB and AFBK, AN69ST haemofilter (same size as used run in period) will be used. Blood and dialysate flow rate will be the same as well as the infusion flow rate. The bath preparation will be the same in both treatments, but not the potassium level. Bath conductivity must be set to obtain the same sodium bath content as the previous bicarbonate dialysis treatment. During the treatment, any additional intake of potassium must be avoided.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Aim of the study is to evaluate the efficacy of AFB potassium-profiled dialysis in the reduction of the number of cardiac arrhythmias during the treatment, compared to constant potassium AFB.

Secondary outcome measures
Not provided at time of registration

Overall study start date
24/02/2003

Completion date
22/02/2005

Eligibility

Key inclusion criteria
1. End stage renal disease (ESRD) patients
2. Duration of renal replacement therapy (RRT) for at least the last six months
3. Three times a week dialysis schedule
4. Patients who, at the time of admission to the study, are being treated with bicarbonate dialysis
5. Age greater than 18 years old

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24 patients (Italian and French dialysis centres)

Key exclusion criteria
1. Patients older than 80 years
2. Patients on antiarrhythmogenic treatment or antihypertensive treatment, which have a declared effect on cardiac rhythm
3. Patients receiving pacemaker or cardiac stimulator
4. Patients on variable digitalis dosage
5. Patients in hypokalemia

Date of first enrolment
24/02/2003

Date of final enrolment
22/02/2005

Locations

Countries of recruitment
France

Italy

Study participating centre
Azienda Ospedaliera Policlinico Sant'Orsola-Malpighi
Bologna
Italy
40128

Sponsor information

Organisation
Hospal S.p.A. (Italy)

Sponsor details

Via Ferrarese 219/9
Bologna
Italy
40128

Sponsor type
Industry

ROR
https://ror.org/02kf9ya90

Funder(s)

Funder type
Industry

Funder Name
Hospal S.p.A. (Italy)

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	01/12/2005		Yes	No