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A European study on acetate free biofiltration versus bicarbonate dialysis (quality control)

Submission date	Recruitment status	[_] Prospectively registered
14/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/07/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/09/2008	Urological and Genital Diseases	[_] Record updated in last year

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
It is a known fact that quality of life is poor in a large proportion of dialysis patients and that life expectancy is four to six times shorter than in non-dialysed subjects. Much effort is thus required to improve clinical results in terms of cost-effectiveness, reducing complications, and improving the quality of life being offered. Adequate dialysis treatments and biocompatibility may not only affect the acute intradialysis events, but may also have an impact on interdialysis morbidity and possible long-term complications.

Acetate free biofiltration (AFB) is a dialysis treatment based on a buffer-free dialysate and a bicarbonate infusion in the post-dilution mode. AFB has been used for both children and adults, favourably affecting the acid-base balance and the nutritional indexes.

Furthermore, a lot of studies have shown that AFB can improve cardiovascular stability during ultrafiltration and reduce dialysis symptoms. Nevertheless, all the studies performed so far have been short-term, since the monitoring time has been one year or less, and so the long-term effects of AFB on the clinical outcome remains to be established.

On theoretical grounds, a dialytic procedure capable of improving small and medium size solute clearance, vascular tolerance, acid-base equilibrium correction, and membrane-associated reactions, seems to possess the characteristics to improve the long-term clinical results by slowing down or preventing the onset of complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee approval given by the ethical committee of the Hospital Sant' Orsola-Malpighi on the 25th January 1998 (ref: 139 SC).

Study design
Prospective, randomised, long-term study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Renal failure requiring haemodialysis

Interventions
AFB and bicarbonate dialysis will be carried out in line with the protocols normally used in dialysis centres.

AFB will be conducted using haemodialysers with AN69 membranes and infusing a sodium bicarbonate solution with a concentration to be chosen between 145 mEq/l and 167 mEq/l in such a quantity as to guarantee a post-dialysis bicarbonatemia between 27 and 30 mEq/l.

Both AFB and bicarbonate dialysis will be conducted using haemodialysers with controlled ultrafiltration rate.

For the bicarbonate dialysis we require the use of a biocompatible membrane, such as AN69, or a low-flux membrane such as low-flux synthetic or cellulose-modified membrane (ultrafiltration rate less than 20).

The inclusion of AN69 in bicarbonate dialysis will allow us to separate the role of the membrane from that of the dialysis methodology.

Ratio of the pre- and post-dialysis urea concentrations (KT/V) = 1,2 and, at any rate, the same for the two dialysis methods within the same Centre. The KT/V is calculated with Daugirdas second generation formula.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sodium bicarbonate

Primary outcome measure
The primary aim of this multicentric trial is to verify, in a large group of patients, the long-term outcomes in term of mortality rate between AFB and bicarbonate dialysis.

Secondary outcome measures
The secondary aims are to verify the clinical effects of AFB on intra and inter-dialytic symptoms, metabolic and nutritional indexes, morbidity, patients well-being and quality of life.

Overall study start date
01/10/1997

Completion date
07/01/2000

Eligibility

Key inclusion criteria
All new patients (who started haemodialysis up to ten months prior to the start of the protocol) defined as critical will be included in the study after an adequate information about the aims of the study.

Critical patients are defined as such if they present at least one of the following conditions:
1. Diabetes
2. Age equal or over 60 years
3. Cardiovascular instability (defined as a frequency of hypotensive episodes in more than 20% of dialysis sessions, or independently of frequency, if hypotension is accompanied by angina or major arrhythmia's)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
No. of patients: more or equal to 400

Key exclusion criteria
1. Age greater than 78 years
2. Active neoplasia
3. Severe cardiopathies (New York Heart Association [NYHA] Class III & Class IV)
4. Decompensating cirrhosis
5. Poor vascular access function (pump flow (Qb) less than 200 ml/m or need for single needle system)
6. Previous continuous ambulatory peritoneal dialysis (CAPD) treatment or kidney transplant
7. On waiting list for kidney transplant

Date of first enrolment
01/10/1997

Date of final enrolment
07/01/2000

Locations

Countries of recruitment
Czech Republic

France

Germany

Italy

Spain

Study participating centre
Azienda Ospedaliera Policlinico Sant'Orsola Malpighi
Bologna
Italy
40138

Sponsor information

Organisation
Hospal S.p.A. (Italy)

Sponsor details
Via Ferrarese
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Bologna
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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