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Scandinavian Prospective Randomised Outcome Study of Hemofiltration and Hemodialysis in Incident Dialysis Patients

Submission date
29/03/2006

Recruitment status
No longer recruiting

Registration date
27/04/2006

Overall study status
Completed

Last Edited
31/05/2011

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym
PROFIL

Study objectives
As compared with hemodialysis (HD), on-line, predilution hemofiltration (HF) reduces the development of left ventricular hypertrophy (LVH), decreases overall morbidity, and retards the loss of residual renal function in incident dialysis patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Karolinska Institute Ethics Review Board 29/12/1999, reference number: 99-292

Study design
Prospective, randomised, controlled, parallel group design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
End stage renal disease patients starting dialysis treatment

Interventions
Two different modes of dialysis, conventional hemodialysis (HD) versus hemofiltration (HF)

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The objective of this study is to compare the effect of treatment with pre-dilution HF and HD, respectively, on left ventricular mass index (LVMI) during 1 to a maximum of 3 years follow up

Key secondary outcome(s))
To compare the effect of HF and HD with respect to:
1. Mortality (all causes)
2. Hospitalisation (number of occasions, total number of days in hospital)
3. Blood pressure (antihypertensive drug index)
4. Dose of recombinant human erythropoietin (rHuEPO) needed to keep hemoglobin at target level
5. Infections (antibiotic drug index)
6. Serum lipids
7. Patients subjective evaluation of intra- and inter-dialytic symptoms

8. Residual renal function
9. Cost effectiveness

Completion date
28/02/2006

Eligibility

Key inclusion criteria
1. Male and female patients with chronic renal failure
2. Age ≥20 and ≤80 years
3. Dialysis treatment <3 months
4. Expected time in HD at treatment site >1 year

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. History of myocardial infarction within 3 months
2. Unstable angina
3. Severe cardiac valvular disease
4. Severe cardiac failure (New York Heart Association [NYHA] III-IV)
5. Disseminated malignancy
6. Expected time in hemodialysis <1 year
7. Participation in another study, which may interfere with the present study
8. Unwillingness to undergo the investigations and follow-up required in the protocol
9. Access to the circulation by central venous catheter >3 months
10. Body weight ≥100 kg

Date of first enrolment
15/05/2000

Date of final enrolment
28/02/2006

Locations

Countries of recruitment
Denmark

Sweden

Study participating centre
Department of Clinical Science
Stockholm
Sweden
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Sponsor information

Organisation
Gambro Corporate Research (Sweden)

ROR
https://ror.org/05mw5ed57

Funder(s)

Funder type
Industry

Funder Name
Study monitor provided by Gambro Corporate Research; financial support to participating clinics in relation to patient enrollment came from Gambro Svenska Försäljnings AB

Results and Publications

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	01/03/2011		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes