

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

Submission date 29/03/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/04/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/05/2011	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.profilstudy.org>

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

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

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

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 measure

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

Secondary outcome measures

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

Overall study start date

15/05/2000

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

Age group

Adult

Sex

Both

Target number of participants

48

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

S 141 86

Sponsor information

Organisation

Gambro Corporate Research (Sweden)

Sponsor details

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Sponsor type

Industry

ROR

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

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	01/03/2011		Yes	No