ISRCTN43474447 https://doi.org/10.1186/ISRCTN43474447

The effect of Membrane Permeability on End-Stage Renal Disease (ESRD) patient Outcome

Submission date 01/08/2007	**Recruitment status** No longer recruiting
Registration date 23/08/2007	**Overall study status** Completed
Last Edited 28/08/2013	**Condition category** Urological and Genital Diseases

[_] Prospectively registered
[X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
MPO

Study objectives
To test whether the survival of ESRD patients treated with bicarbonate hemodialysis using high-flux membranes is better than that of those treated with bicarbonate hemodialysis using low-flux membranes.

This trial is also registered with the Cochrane Renal Group Registry (registration number: CRG 090500013).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local and national ethics approvals were obtained for all study sites according to the national legislations.

Study design
Open, prospective, centrally randomised, international, multi-centre study.

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
Chronic kidney disease stage 5

Interventions
Chronic hemodialysis with high-flux membranes vs low-flux membranes.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
All-cause mortality, determined upon occurence throughout the complete study period.

Secondary outcome measures
1. Mortality due to infections
2. Mortality due to cardiovascular causes
3. Morbidity due to all causes
4. Morbidity due to infections
5. Morbidity due to problems related to vascular access
6. Pre-dialysis beta2-microglobulin levels
7. Pre-dialysis plasma levels of Advanced Glycosylation End-products (AGE)
8. Hematocrit levels and related rHu-EPO dose
9. Triglycerides and the High Density Lipoproteins (HDL) / Low Density Lipoprotein (LDL) cholesterol ratio
10. Pre-dialysis bicarbonate
11. Nutritional parameters
12. Protein Catabolic Rate (PCR)
13. Residual renal function

1 to 5 above were determined upon occurence throughout the complete study period, and the other parameters in 6-monthly intervals.

Overall study start date
15/12/1998

Completion date
15/07/2006

Eligibility

Key inclusion criteria
1. Age between 18 and 80 years old
2. Up to two months on renal replacement therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
666

Key exclusion criteria
1. Scheduled for renal transplantation from a living donor within the period of the study
2. On hemodialysis after renal transplantation
3. Serious clinical conditions:
3.1. Nephrotic syndrome
3.2. Active malignancies
3.3. Current therapy with immunosuppressive agents
3.4. Severe congestive heart failure despite maximal therapy (New York Heart Association [NYHA] class IV)
3.5. Unstable angina pectoris
3.6. Active systemic infections (i.e. tuberculosis, systemic fungal infection, AIDS, hepatitis)
3.7. Chronic pulmonary disease requiring supplementary oxygen
3.8. Cirrhosis with encephalopathy

Date of first enrolment
15/12/1998

Date of final enrolment
15/07/2006

Locations

Countries of recruitment
Belgium

France

Germany

Greece

Italy

Poland

Portugal

Spain

Sweden

Study participating centre
Department of Nephrology and Dialysis
Lecco
Italy
23900

Sponsor information

Organisation
Fresenius Medical Care (Germany)

Sponsor details
Else-Kroener-Strasse 1
Bad Homburg
Germany
61352

Sponsor type
Industry

Website
http://www.fmc-ag.com/

ROR
https://ror.org/04sk0bj73

Funder(s)

Funder type
Industry

Funder Name
Fresenius Medical Care, for organisational support, monitoring and central laboratoy analysis (Germany)

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?
Protocol article	protocol	01/03/1999		Yes	No
Results article	results	01/07/2011		Yes	No