

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

Submission date
01/08/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date
23/08/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
28/08/2013

Condition category
Urological and Genital Diseases

☐ 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 occurrence 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 occurrence 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 laboratory 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