‘**E**studi de **S**upervivència d’**H**emodiafiltració **O**n-**L**ine’ (Estudi ESHOL)

Estudi multicèntric de la SCN
Grup de treball d’HDF on-line
Coordinador: Dr. Francesc Maduell

7 de febrer 2013

Períodes d'inclusió i finalització del estudi.

- **Període d'inclusió: Maig 2007 – Sep. 2008**
- **Duració 3 anys**
- **Final del estudi: Septembre 2011!**
- **Publicació del estudi 15-02-2013**

ESHOL

- **Cumplimentació dades: Oct 2011 – Abril 2012!**
- **Resoldre els queris de la CRO: Feb-Abril 2012**
- **Anàlisis estadístic i redacció manuscrit: Maig-Setembre 2012**

Centres Participants

1. Cetirsa Barcelona
2. Hospital Sant Antoni Abat, Vilanova
3. Institut Nefrològic de Granollers
4. Centre Diàlisi Baix Llobregat
5. Reus Medical
6. Institut Nefrològic Hospitalet
7. Cetirsa Terrassa
8. Institut Nefrològic Diagonal
9. Hospital Clínic Barcelona
10. Institut Nefrològic de Julio Verne
11. Institut Nefrològic Santa Tecla, Tarragona
12. Fundació Althaia
13. Centre Diàlisi Bonanova
14. Institut Hemodiàlisi Barcelona
15. Fundació Puigvert
16. Hospital General de Vic
17. Hospital Josep Trueta
18. Centre Diàlisi Mataro
19. Hospital Bellvitge
20. Hospital de Terrassa
21. Centre Diàlisi Verge Montserrat
22. Centre Secretari Coloma
23. Hospital de Figueres
24. Centre Diàlisi Nephros
25. Hospital Arnau de Vilanova, Lleida
26. Hospital de la Santa Creu, Tortosa
27. Clínica Girona

Institutions and investigators participating in the ESHOL study

CETIRSA, Barcelona: B. Insensé, C. Perez, T. Feliz; Hospital San Antonio Abad, Vilanova i la Geltru: M. Barbetta, C. Soto; Fresenius Medical Care, Granollers: A. Juan, O. Ibrik; Diaverum Baix Llobregat, Hospitalet: J. Carreras; Fresenius Medical Care, Hospitalet: Miguel Hueso, J. Nin, A. Fernández; Fresenius Medical Care, Reus: M. Arruche, C. Sánchez, J. Vidiella; Fresenius Medical Care Diagonal, Barcelona: F. Barbosa, M. Chiné, S. Hurtado; CETIRSA, Terrassa: J. Llibre, A. Ruiz, M. Serra, M. Salvó, T. Puyuelo; Hospital Clínic, Barcelona: M. Carrera, V. de la Fuente, N. Fontseré, M. Arias; Fresenius Medical Care Julio Verne, Barcelona: A. Merín, MC. Morgades, J.L. Anson; Fundació Althaia, Manresa: J. Mòdol, E. Moliner, A. Ramirez; Hospital Santa Tecla, Tarragona: J. Aguilera, M. Alvarez; Diaverum Bonanova, Barcelona: B. de la Torre, M. Molera; Diaverum IHB, Barcelona: J. Casellas, G. Martín; Fundació Puigvert, Barcelona: E. Andrés, E. Coll; Hospital Josep Trueta, Girona: M. Valles; Hospital General, Vic: E. Castellote; Diaverum, Mataró: JM. Casals, J. Gabàs, M. Romero; Hospital Universitari Bellvitge, Hospitalet: X. Fulladosa, C. Ortega; Hospital de Terrassa: M. Ramírez de Arellano; Diaverum Verge de Montserrat, Santa Coloma: A. Pelegrí, M. el Manouari, N. Ramos; Centre Secretari Coloma, Barcelona: J. Bartolomé; Hospital de Figueres, R. Sans; Hospital Arnau de Vilanova, Lleida: E. Fernández, F. Sarró; Hospital Santa Creu, Tortosa: T. Compte; Diaverum Nephros, Barcelona: F. Marco, R. Mauri; Clínica Girona: J. Bronsoms.

SCN
SOCIETAT CATALANA DE NEFROLOGIA

ESHOL

Difusió del estudi

ORIGINAL ARTICLE

JNEPHROL 2011; 24(02): 196-202

DOI:10.5301/JN.2010.386

Design and patient characteristics of ESHOL study, a Catalonian prospective randomized study

Francisco Maduell [1], Francesc Moreso [2], Mercedes Pons [3], Rosa Ramos [4], Josep Mora-Macià [5], Andreu Foraster [6], Jordi Soler [7], Josep M. Galceran [8], Alberto Martinez-Castelao [9]

On behalf of the Online Hemodiafiltration Study Group from the Catalonian Society of Nephrology [9]

[1] Department of Nephrology, Hospital Clínic, Barcelona - Spain
[2] Department of Nephrology, Hospital Universitari Vall d'Hebron, Barcelona - Spain
[3] CETIRSA, Barcelona - Spain
[4] Department of Nephrology, Hospital San Antonio Abad, Vilanova i la Geltru - Spain
[5] Fresenius Medical Care, Granollers - Spain
[6] Diaverum Baix Llobregat, Hospitalet - Spain
[7] Fresenius Medical Care, Reus - Spain
[8] Fundació Althaia, Manresa - Spain
[9] Department of Nephrology, Hospital Universitari Bellvitge, Barcelona - Spain

Abstract

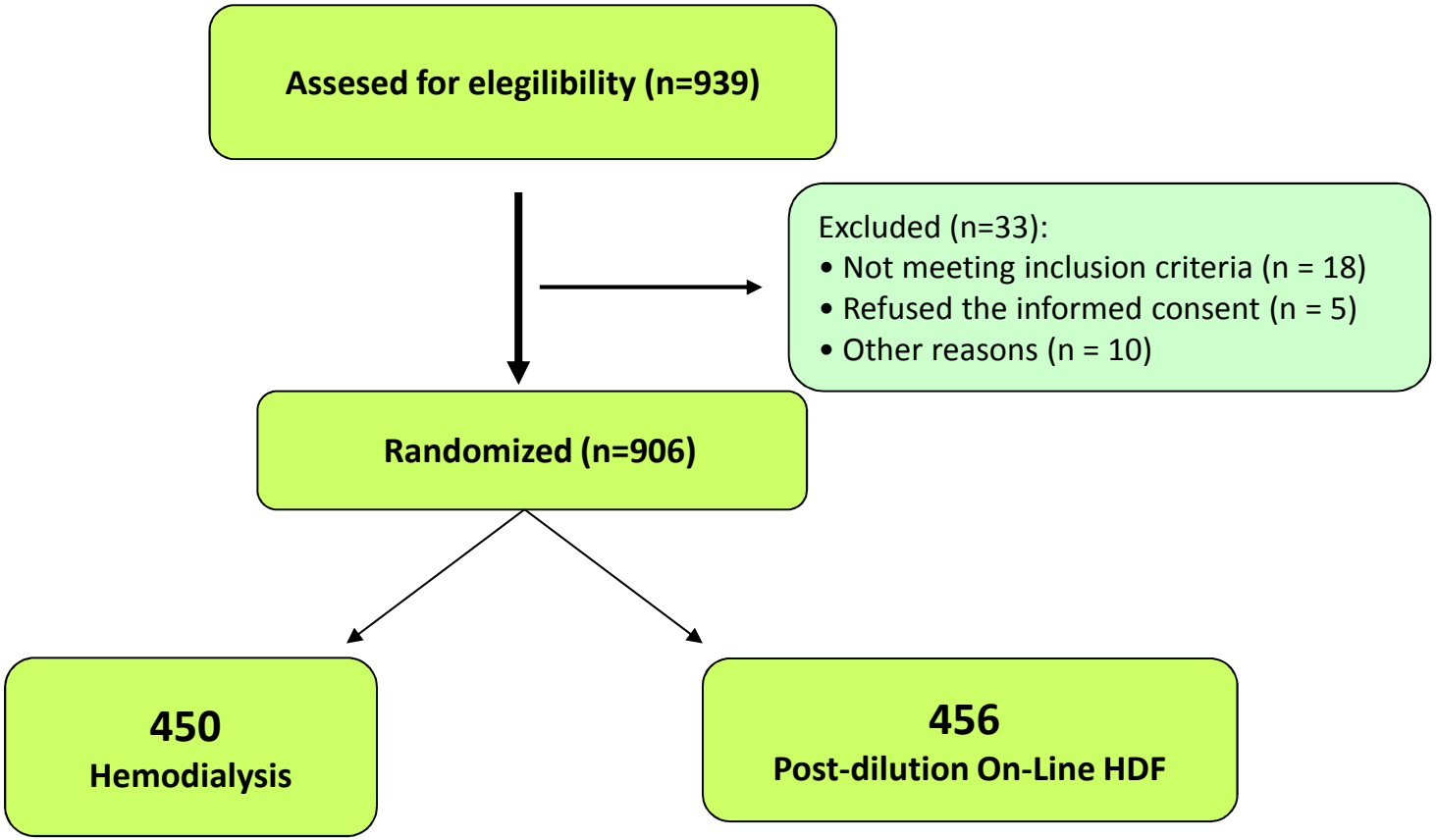
Background: Retrospective studies showed that on-line hemodiafiltration (OL-HDF) is associated with a risk reduction of mortality over standard hemodialysis (HD) in patients with end-stage renal disease. Until now, no information was available from prospective randomized clinical trials.

Methods: A prospective, randomized, multicenter, open study was designed to be conducted in HD units from Catalonia (Spain). The aim of the study is to compare 3-year survival in prevalent end-stage renal disease patients randomized to OL-HDF or to continue on standard HD. The minimum sample size was calculated according to Catalonian mortality of patients on dialysis and assuming a risk reduction associated with OL-HDF of 35% (1-sided $p<0.05$ and a statistical power of 0.8) and a rate of dropout due to renal transplantation or loss to follow-up of 30%.

Results: From May 2007 to September 2008, 906 patients were included and randomized to OL-HDF (n=456) or standard HD (n=450). Demographics and analytical data at the time of randomization were not different between both groups of patients. Patients will be followed during a 3-year period.

Conclusion: The present study will contribute to evaluating the benefit for patient survival of OL-HDF over standard HD.

Key words: *Convective therapies, Dialysis adequacy, Mortality, On-line hemodiafiltration*



Endpoint Primario: Mortalidad.

Duración del estudio: 3 años

TABLE I
DEMOGRAPHIC CHARACTERISTICS AND DIALYSIS PARAMETERS IN RANDOMIZED PATIENTS

Characteristics	All patients (n=906)	Hemodialysis (n=450)	Online HDF (n=456)
Age, years	65.4 ± 14	66.3 ± 14	64.5 ± 14
Male sex, no. (%)	606 (66.9%)	289 (64.2%)	317 (69.5%)
Diabetes, no. (%)	226 (24.9%)	122 (27.1%)	104 (22.8%)
Charlson comorbidity Index score	6.6 ± 2.3	6.7 ± 2.3	6.4 ± 2.4
Time on dialysis, months	48.8 ± 64	50.3 ± 71	47.4 ± 55
Vascular access, no. (%)			
Fistula	777 (85.8%)	375 (83.3%)	402 (88.1%)
Graft	33 (3.6%)	18 (4.0%)	15 (3.3%)
Catheter	95 (10.5%)	56 (12.4%)	39 (8.5%)
Dialysis time, minutes	235 ± 19	234 ± 21	236 ± 18
Qb, ml/min	387 ± 64	381 ± 66	393 ± 60*
Qd, ml/min	541 ± 125	529 ± 120	552 ± 128*
Body weight, kg	67.4 ± 14	66.8 ± 13	67.9 ± 14
High-flux membrane, no. (%)	848 (93.7%)	412 (91.8%)	436 (95.6%)
Kt/V	1.66 ± 0.36	1.66 ± 0.40	1.67 ± 0.31
URR, %	74.3 ± 17	74.2 ± 14	74.3 ± 20
nPCR, g/kg	1.09 ± 0.23	1.09 ± 0.22	1.10 ± 0.24

TABLE II
PREDIALYSIS BIOCHEMICAL PARAMETERS AT ENROLLMENT

Characteristics	All patients (n=906)	Hemodialysis (n=450)	Online HDF (n=456)
C-reactive protein, mg/L	6.3 (4.9-13.0)	5.7 (4.9-12.3)	7.0 (4.3-13.7)
Blood urea nitrogen, mg/dL	61.0 (50-73)	61.0 (51-75)	61.1 (50-71)
Creatinine, mg/dL	7.8 (6.3-9.6)	7.7 (6.2-9.6)	8.0 (6.4-9.7)
Bicarbonate, mmol/L	21.5 (20-24)	21.5 (20-24)	21.5 (20-24)
Sodium, mmol/L	139 (137-141)	139 (136-141)	139 (137-141)
Potassium, mmol/L	5.3 (4.7-5.8)	5.4 (4.8-5.9)	5.2 (4.67-5.8)
Uric acid, mg/dL	5.6 (4.9-6.2)	5.6 (4.8-6.2)	5.6 (4.9-6.3)
Albumin, g/dL	4.1 (3.8-4.4)	4.1 (3.8-4.4)	4.1 (3.8-4.4)
Calcium, mg/dL	9.0 (8.6-9.5)	9.0 (8.6-9.5)	9.0 (8.6-9.5)
Phosphorus, mg/dL	4.5 (3.6-5.5)	4.4 (3.5-5.4)	4.6 (3.7-5.6)
Intact parathyroid hormone, pg/mL	209 (113-360)	209 (122-359)	209 (105-362)
β_2-Microglobulin, mg/L	22.7 (19-28)	22.8 (19-29)	22.1 (18-28)

Values are medians (interquartile range).
HDF = hemodiafiltration.

TABLE III
HEMATOLOGICAL PARAMETERS AND BLOOD PRESSURE FINDINGS AT ENROLLMENT

Characteristics	All patients (n=906)	Hemodialysis (n=450)	Online HDF (n=456)
Hemoglobin, g/dL	12.0 (11.0-13.0)	12.0 (11.0-12.8)	12.1 (11.0-13.0)
Hematocrit, %	37.5 (35-41)	37.1 (35-40)	37.7 (35-40)
Transferrin saturation, %	26.0 (19-37)	27.0 (20-38)	25.5 (19-35)
Ferritin, ng/mL	336 (210-499)	360 (231-500)	322 (189-494)
Iron doses, mg/week	25.0 (10-50)	25.0 (0-50)	25.0 (12.5-50)
ES agents, no. (%)			
EPO	413 (45.6%)	209 (46.2%)	204 (44.7%)
Darbepoetin	409 (45.1%)	206 (45.8%)	203 (44.5%)
CERA	11 (1.2%)	5 (1.1%)	6 (1.3%)
EPO dosage, IU/kg per week	6,000 (4,000-12,000)	6,000 (4,000-11,000)	6,000 (4,000-12,000)
Systolic blood pressure, mm Hg	136 (120-152)	137 (120-152)	134 (120-152)
Diastolic blood pressure, mm Hg	70 (62-80)	70 (60-80)	71 (64-84)
Patients on antihypertensive therapy, no. (%)	530 (58.6%)	260 (57.9%)	270 (59.2%)
Phosphate binding, pills/day	3 (2-5)	3 (2-5)	3 (2-5)

Values are number (%) or median (interquartile range) where appropriate.
CERA = continuous erythropoietin receptor activator; EPO = epoetin-alpha or epoetin-beta; ES = erythropoiesis-stimulating; HDF = hemodiafiltration.

Finalment els resultats del estudi ESHOL s'han acceptat per publicar a la revista JASN.

Es preveu la publicació per el 15 de febrer i s'ha solicitat que sigui en *open acces.*

Agraïments

A tots el centres participants i a cadascun dels quasi 100 investigadors que han participat en el estudi.

Agrair la col·laboració i suport de la indústria: