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An evaluation of improving dialysis adequacy in large haemodialysis patients: the double dialyser study

Submission date	Recruitment status	[_] Prospectively registered
19/09/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/08/2021	Urological and Genital Diseases	

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
15603

Study information

Scientific Title
An evaluation of improving dialysis adequacy in large haemodialysis patients: the double dialyser study

Study objectives
Health related quality of life for patients treated with a strategy to increase dialysis adequacy will be similar to health related quality of life when treated with standard dialysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Conjoint Medical Ethics Board of the University of Calgary on the 7th December 2000 (ref: 15603).

Study design
Randomised, controlled, cross-over study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Kidney failure/haemodialysis

Interventions
All patients were treated for 4 weeks with "4 hours of haemodialysis" three times per week for one month (the run-in period). Then all patients were randomised to receive each of the four noted treatments (below), for six weeks each, in a random order. There was no wash out period between each of the four treatment periods. The intention was that all patients would receive each of the four treatments. Total study time was 24 weeks, plus the 4 week run-in.

1. Standard haemodialysis: four hours of haemodialysis three times per week - haemodialysis was undertaken using a high flux, high efficiency polysulfone dialyser (i.e., F80A dialyser [Fresenius, Inc, Walnut Creek, CA] or equivalent), with a blood flow of 350 - 400 ml/min and a dialysate flow of 500 ml/min
2. Increased dialysate flow: patients received standard dialysis for four hours three times per week but the dialysate flow rate was 800 ml/min rather than 500 ml/min

3. Increased dialysis time: haemodialysis for 4.5 hours, three times per week
4. Double dialyser: patients received haemodialysis for four hours three times per week with two F80A dialysers connected by a Y-connector in a parallel configuration during each run using the method described by Powers et al. Dialysate flow was 800 ml/min

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
'End-Stage Renal Disease (ESRD) symptoms' domain of the Kidney Disease Quality of Life Short Form (KDQOL-SF) measured at the end of each 6-week treatment session.

Secondary outcome measures
1. Health Utility Index mark 2 (HUI 2) utility score, evaluated during the last week of the treatment (i.e. during week 6 of each treatment period)
2. Exploratory measures of Health-Related Quality Of Life (HRQOL): other domains of the Kidney Disease Quality of Life (KDQOL) and 36-item Short Form health survey (SF-36), evaluated during the last week of the treatment (i.e. during week 6 of each treatment period)

Overall study start date
01/07/2001

Completion date
01/07/2004

Eligibility

Key inclusion criteria
1. Patients on a stable regimen of haemodialysis greater than or equal to 3 months
2. Dry weight greater than or equal to 80 kg
3. Kt/V less than 1.2 on two occasions in the previous 6 months or requirement for greater than 12 hours of haemodialysis per week because of a history of inadequate dialysis
4. Blood flow rate greater than 350 ml/min through a well functioning access
5. Aged greater than 18, both sexes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
18

Total final enrolment
18

Key exclusion criteria
1. Scheduled renal transplant in the next 6 months
2. Contraindication to intradialytic anticoagulation
3. Requirement for greater than 4.5 hours of haemodialysis three times per week for the purpose of volume removal due to excessive interdialytic weight gains or intradialytic hypotension/cramping
4. Failure to provide informed consent

Date of first enrolment
01/07/2001

Date of final enrolment
01/07/2004

Locations

Countries of recruitment
Canada

Study participating centre
Foothills Medical Center
Calgary
Canada
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Sponsor information

Organisation
Kidney Foundation of Canada (Canada)

Sponsor details
300-5165 Sherbrooke Street West
Montreal
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Sponsor type

Research organisation

Website
http://kidney.ca

ROR
https://ror.org/019a0gk53

Funder(s)

Funder type
Research organisation

Funder Name
Kidney Foundation of Canada (Canada)

Alternative Name(s)
La Fondation canadienne du rein, KFOC

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

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		19/07/2009	05/08/2021	Yes	No