

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

**Submission date**  
19/09/2007

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
27/09/2007

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
05/08/2021

**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

### Contact name

Dr Braden Manns

### Contact details

Foothills Medical Center

1403 -29th St NW

Calgary

Canada

T2N 2T9

+1 403 944 2595

Braden.Manns@calgaryhealthregion.ca

## 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

T2N 2T9

**Sponsor information****Organisation**

Kidney Foundation of Canada (Canada)

**Sponsor details**

300-5165 Sherbrooke Street West

Montreal

Canada

H4A 1T6

+1 514 369 4806

webmaster@kidney.ca

**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?
<a href="#">Results article</a>		19/07/2009	05/08/2021	Yes	No