Effect of increased convective clearance by on-line hemodiafiltration on all cause and cardiovascular mortality in chronic hemodialysis patients. The Dutch CONvective TRAnsport STudy (CONTRAST).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21199

Source
Nationaal Trial Register

Brief title
CONTRAST

Intervention

Outcome measures

Primary outcome

Cardiovascular morbidity and mortality. This is a composite endpoint comprising fatal and non-fatal myocardial infarction and stroke, and vascular death (death due to vascular disease). Also all-cause mortality is considered a primary endpoint.

Secondary outcome

Changes in carotid intima media thickness (cIMT), aortic pulse wave velocity (PWV), left ventricular mass index (LVMi), interdialytic blood pressure, laboratory assessments (oxidative stress; acute phase response; lipid profile; various), quality of life, and nutritional state.

Study description

Background summary

Today, an increasing number of patients with end stage renal failure (ESRF) is treated with on-line hemodiafiltration (HDF). This practice is based on the assumption that the high incidence of cardiovascular (CV) disease, as observed in patients with ESRF, is at least partially related to the retention of uremic toxins in the middle and large-middle molecular (MM) range. As HDF lowers these molecules more effectively than hemodialysis (HD), it has been suggested that this treatment improves CV outcome, if compared to standard HD. Thus far, no definite data on the effects of HDF on CV parameters and/or clinical end-points are available.
As the accumulation of MM weight substances has been implicated in increased oxidative stress and endothelial dysfunction, a reduction of these compounds might improve these derangements. In addition, cardiac dysfunction, atherosclerosis (as measured by left ventricular mass index [LVMi], carotid intima media thickness [CIMT]) and vascular stiffness (as measured by pulse wave velocity [PWV]) might be reduced during HDF, as compared to low-flux HD.
Therefore, we propose a prospective, randomized multicenter trial, comparing (on-line) HDF with HD. After a stabilization period, an expected number of 800 chronic HD patients will be randomized to either HDF or low-flux HD for three years. Primary end points are all cause mortality and combined CV events and mortality. In addition, LVMi, PWV, CIMT and various parameters of oxidative stress, acute phase reaction (APR) and endothelial function will be assessed and compared between treatment groups.
This study will provide strong evidence on the efficacy of HDF compared to low flux HD on CV morbidity and mortality, which is currently lacking but urgently needed. It is possible that the outcome of this study will affect current clinical practice considerably. Moreover, the study will point towards the mechanisms underlying the effects of HDF.

Study objective

The high incidence of cardiovascular disease in patients with end stage renal disease (ESRD) is related with the accumulation of uremic toxins in the middle and large-middle molecular weight range. As online hemodiafiltration (HDF) lowers these molecules more effectively than standard hemodialysis (HD), it is suggested that this treatment may improve cardiovascular outcome.

Intervention

Patients will be randomised between:

- online hemodiafiltration
- (continuation with) low-flux hemodialysis

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients treated by HD 2 or 3 times a week, for at least 2 months;
2. Patients able to understand the study procedures;
3. Patients willing to provide written informed consent.

Exclusion criteria

1. Current age younger than 18 years treatment by HDF or high flux HD in the preceding 6 months;
2. Severe incompliance life expectancy < 3 months due to non renal disease;
3. Participation to other clinical intervention trials evaluating cardiovascular outcome.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2004
Enrollment:	800
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-12-2004
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8
NTR-old	NTR24
Other	: grant C02.2019 (Dutch Kidney Foundation)
ISRCTN	ISRCTN38365125

Study results

Summary results
Penne EL, Blankestijn PJ, Bots ML, van den Dorpel MA, Grooteman MP, Nube MJ, van der Tweel, I, Ter Wee PM: Effect of increased convective clearance by on-line hemodiafiltration on all cause and cardiovascular mortality in chronic hemodialysis patients - the Dutch CONvective TRAnsport STudy (CONTRAST): rationale and design of a randomised controlled trial [ISRCTN38365125]. Curr.Control Trials Cardiovasc.Med. 6:8, 2005