

Effect of increased convective clearance by on-line haemodiafiltration on all cause and cardiovascular mortality in chronic haemodialysis patients: the Dutch CONvective TRANsport Study

Submission date

16/05/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

16/05/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

07/01/2015

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

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00205556

Protocol serial number

NTR24

Study information

Scientific Title

Effect of increased convective clearance by on-line haemodiafiltration on all cause and cardiovascular mortality in chronic haemodialysis patients: the Dutch CONvective TRANsport STudy

Acronym

CONTRAST

Study objectives

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 Haemodiafiltration (HDF) lowers these molecules more effectively than standard Haemodialysis (HD), it is suggested that this treatment may improve cardiovascular outcome.

On 24/01/2008 the following changes were made to the trial record:

1. The anticipated end date was changed from 31/12/2009 to 31/12/2010.
2. The target number of participants was changed from 800 to 700.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Medical Ethics Review Committee of the Vrije Universiteit Medical Center in Amsterdam, the Netherlands. Approved on 31/07/2003, ref: 2003/97. Amendment to protocol approved on 28/06/2007.

Primary study design

Interventional

Study design

Multicentre randomised active-controlled parallel-group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic haemodialysis (HD)

Interventions

Patients will be randomised between:

1. Online haemodiafiltration
2. (Continuation with) low-flux haemodialysis

Added 24/01/2008:

Follow up: Variable follow-up period of 1-7 years (in previous version of protocol: fixed follow up of 3 years)

Intervention Type

Procedure/Surgery

Primary outcome(s)

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.

Key secondary outcome(s)

Current secondary outcome measures as of 20/01/2011:

Changes in:

1. Carotid Intima Media Thickness (cIMT)
2. Aortic Pulse Wave Velocity (PWV)
3. Left Ventricular Mass index (LVMI)
4. Interdialytic blood pressure
5. Laboratory assessments (oxidative stress; acute phase response; lipid profile; various)
6. Quality of life
7. Nutritional state
8. Anemia management: hemoglobin levels and erythropoietin use/resistance (addendum to the protocol on this issue has been approved by ethical committee in October, 2003)
9. Cost utility analysis (addendum to the protocol on this issue has been approved by the ethical committee in April, 2008)
10. Hospitalization days
11. Hospital admission for infection
12. Hospital admission for any cause
13. Blood pressure and antihypertensive medication
14. Residual kidney function
15. Laboratory parameters on mineral bone disease and medication
16. Treatment delivery (dialysis efficiency Kt/V urea, ultrafiltration volume, and only HDF: convection volume)

Previous secondary outcome measures:

Changes in:

1. Carotid Intima Media Thickness (cIMT)
2. Aortic Pulse Wave Velocity (PWV)
3. Left Ventricular Mass index (LVMI)
4. Interdialytic blood pressure
5. Laboratory assessments (oxidative stress; acute phase response; lipid profile; various)
6. Quality of life
7. Nutritional state

Completion date

31/12/2010

Eligibility

Key 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Current age less than 18 years treatment by Haemodiafiltration (HDF) or high flux HD in the preceding 6 months
2. Severe incomppliance life expectancy less than 3 months due to non-renal disease
3. Participation to other clinical intervention trials evaluating cardiovascular outcome

Date of first enrolment

01/06/2004

Date of final enrolment

31/12/2010

Locations**Countries of recruitment**

Netherlands

Study participating centre

Vrije University Medical Centre (VUMC)

Amsterdam

Netherlands

1007 MB

Sponsor information**Organisation**

Vrije University Medical Centre (VUMC) (The Netherlands)

Organisation

University Medical Center Utrecht (UMCU) (The Netherlands)

Organisation

VU University Medical Center

ROR

<https://ror.org/00q6h8f30>

Funder(s)**Funder type**

Industry

Funder Name

Dutch Kidney Foundation (Nierstichting Nederland) (The Netherlands) (ref: C02.2019)

Alternative Name(s)

Dutch Kidney Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Funder Name

Fresenius Medical Care (The Netherlands)

Funder Name

Gambro (The Netherlands)

Funder Name

Dr E.E. Twiss Fund (The Netherlands)

Funder Name

Roche (The Netherlands)

Alternative Name(s)

F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co., Roche Holdings, Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Funder Name

The International Society of Nephrology (The Netherlands) - Baxter Extramural Grant Program

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2013		Yes	No
Results article	results	01/02/2014		Yes	No
Results article	results	05/02/2014		Yes	No
Results article	results	01/03/2014		Yes	No
Other publications	1.1.	01/01/2005		Yes	No
Other publications	1.2.	20/05/2005		Yes	No
Other publications	Interim report:	15/06/2006		Yes	No
Other publications	Review (this trial mentioned)	01/02/2008		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes

