

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

Study website

<http://www.contrast-ned.nl/>

Contact information

Type(s)

Scientific

Contact name

Dr M.P.C. Grooteman

Contact details

Vrije University Medical Centre (VUMC)

Department of Nephrology

P.O. Box 7057

Amsterdam

Netherlands

1007 MB

+31 (0)20 444 2673

mpc.grooteman@vumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00205556

Secondary identifying numbers

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.

Study design

Multicentre randomised active-controlled parallel-group trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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 measures

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

Overall study start date

01/06/2004

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

Age group

Adult

Sex

Both

Target number of participants

700

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)

Sponsor details

Department of Nephrology
P.O. Box 7057
Amsterdam
Netherlands
1007 MB
+31 (0)20 444 2673
mpc.grooteman@vumc.nl

Sponsor type

University/education

Website

<http://www.vumc.nl/english/>

Organisation

University Medical Center Utrecht (UMCU) (The Netherlands)

Sponsor details

P.O. Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type

University/education

Organisation

VU University Medical Center

Sponsor details

Sponsor type

Not defined

Website

<http://www.vumc.nl/>

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.

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

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?
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
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