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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

Registration date
16/05/2005

Overall study status
Completed

Last Edited
07/01/2015

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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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 incompliance 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
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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