CONVINCE
An international, multi-centre, prospective, randomised, controlled study comparing high-dose Haemodiafiltration (HDF) versus conventional high-flux Haemodialysis (HD).

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON52958

Source
ToetsingOnline

Brief title
CONVINCE

Condition

- Renal disorders (excl nephropathies)

Synonym
End Stage Kidney Disease, renal insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Europese Unie;Horizon 2020;grant agreement No 754803

Intervention

Keyword: end stage kidney disease, haemodiafiltration, haemodialysis, renal insufficiency

Outcome measures

Primary outcome

The primary endpoint is defined as difference in rate for all-cause mortality.

Secondary outcome

The secondary endpoints are:

1. Cause specific mortality (at least cardiovascular and non-cardiovascular

death; others with high frequency may be added);

2. Non-fatal and fatal cardiovascular events;

3. Hospitalisation for infection-related conditions;

4. All cause hospitalisations;

5. patient related experience and outcome measures;

6. Cost effectiveness.

Study description

Background summary

End stage kidney disease (ESKD) ranks among the most severe chronic non-communicable diseases with an unmet medical need, given the high (between 10% and 20%) and stable annual mortality rates in ESKD patients treated with

dialysis. Kidney replacement therapy is necessary when kidney function is below roughly 10% of the normal value. Much effort is put into developing strategies to prevent chronic kidney disease progression. Regenerative medicine is still in the experimental phase and kidney transplantation is only available for a small number of patients. Indeed, the everyday reality is the growing number of dialysis patients. Haemodialysis (HD) treatment is the current standard of care for the vast majority of patients with ESKD. HD is associated with high risks of fatal and non-fatal cardiovascular disease, for infections, hospitalisation and low quality of life. Improvement in the currently available standard is urgently needed.
Over the past decade, an alternative for haemodialysis became available; called haemodiafiltration (HDF). HD and HDF are accepted by regulatory authorities. HDF removes waste products that are accumulated due to kidney failure, more effectively than standard HD. A individual patient-level data meta-analysis of the four recent European randomised controlled trials, which comprised 2753 patients with a median follow up of 2.5 years was recently reported. The results indicate an approximate 22% reduction of mortality risk when convection volume dosages of > 23 L/session, standardised for Body Surface Area (BSA), was used. The main beneficial effect was demonstrated by an observed 30% reduction of cardiovascular mortality and specifically cardiac mortality. Importantly, the pooled analysis also suggests a 31% reduction in sudden death rate of borderline significance. A recent large observational study supports the notion that increased clinical benefit is related to higher dosages. Despite these recent findings, the scientific community remains critical, largely due to results that the beneficial effects might be explained by patient selection (i.e. a healthier patient receives more convection volume). Furthermore, the mechanism(s) of a possible beneficial effect is/are unproven. This also reduces the acceptance of the idea of superiority of HDF.

Study objective

This consortium aims to determine the best possible dialysis treatment by comparing high-dose HDF versus conventional high-flux HD treatment by carrying out a prospective randomised controlled clinical trial addressing clinical endpoints, quality of life and a cost-utility analysis. The CONVINCE study will deliver an answer on the question which intervention gives the best value for money. Therefore, it will be considered a *land mark* study, allowing to publish an *end of discussion* paper.

Study design

A multi-centre, controlled, prospective, randomised, open-label trial with intention-to-treat analyses and a minimum loss to follow-up.

Intervention

Patients will be randomised between high-dose HDF and high-flux HD treatment. Both are currently approved methods of dialysis.

Study burden and risks

As both HD and HDF are current standards of care, the risks are minimal.
At time of randomisation, a physical performance test will be done. During the trial the patient will be asked to complete questionnaires. No other study specific tests will be done. The burden for the patient is minimal.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Signed and dated written Informed Consent Form.
2. Male or female aged >= 18 years.
3. Diagnosed with ESKD.
4. On HD treatment for >= 3 months.
5. Likely to achieve high-dose HDF (>= 23 L adjusted to BSA/session, in post-dilution mode)
6. Willing to have a dialysis session with duration of >= 4 hours, three times a week.
7. Understands study procedures and is able to comply.

Exclusion criteria

1. Severe subject non-compliance defined as severe non-adherence to the dialysis procedure and accompanying prescriptions, especially frequency and duration of dialysis treatment.
2. Life expectancy < 3 months.
3. HDF treatment < 90 days before screening.
4. Anticipated living donor kidney transplantation < 6 months after screening.
5. Evidence of any other diseases or medical conditions that may interfere with the planned treatment, affect subject compliance or place the subject at high risk for treatment-related complications.
6. Participation in any other study will be discussed with and decided by the Executive Board depending on the extent of interference on this study. Registries are expected to be approved.
7. Unavailable >= 3 months during the study conduct for study visits.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	05-09-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-10-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-11-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-12-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	31-01-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-06-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-03-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	21-09-2022
Application type:	Amendment
Review commission:	METC NedMec

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
Other	De studie is geregistreerd in het Nederlands Trial Register onder nummer 7138.
CCMO	NL64750.041.18

Study results