SYMPTOMATIC IMPROVEMENT BY PERITONEAL DIALYSIS IN PATIENTS WITH END STAGE CONGESTIVE HEART FAILURE

Published: 05-02-2010
Last updated: 06-05-2024

To improve symptomatology in severe chronic failure patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON38127

Source
ToetsingOnline

Brief title
Peritoneal dialysis in congestive heart failure.

Condition

- Heart failures

Synonym
cardiac decompensation, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Baxter,Eigen inzet maatschappen Interne Geneeskunde en Cardiologie van deelnemende centra,Roche Nederland BV (staat niet onder Farmaeutische Industrie)

Intervention

Keyword: Congestive heart failure, Peritoneal dialysis, Renal function, Symptomatic improvement

Outcome measures

Primary outcome

1a. Reduction in NYHA classification of symptomatic Congestive Heart Failure at

8 months after start of PD therapy with 2 dwells of Extraneal during 24 hours.

1b. Burden of congestive heart failure: measured by reduction in unfavorable

days (noted by patients in diaries and including days of hospitalization for

CHF-deterioration and death) with 2 dwells of Extraneal during 24 hours.

Secondary outcome

2. QoL measured as general status by the Short-Form 36.

3. QoL measured as health-specific status by the Minnesota Living with Heart

Failure Questionnaire.

4. VO2max measured by a standardized physical exertion 6-minute walk test.

5. Number and length of (re)hospitalizations for CHF, as well as total number

of hospitalizations.

6. (increase) in optimal medication: dose of ACEI, ARB, spironolactone (total

dose/day).

7. Survival: subjects alive at 8 months and thereafter, Kaplan Meier, length

of life, causes of death.

8. Cardiovascular: - improvement in 6 minute walk test;

- reduction in LVH / LVM

9. Renal/PD: - Urinary protein, urinary biomarkers: (KIM-1, NGAL, NAG);

- Residual kidney function (urea +

creatinine clearance), KT/V

- GFR / ERPF / FF with

iothalamate/hippuran

10. Volume status: - extracellular volume with iothalamate

- bio-impedance

11. Neurohumoral: - changes in: PRA, Aldosterone, NT-proBNP, ADH, osmolality

- reduction in peripheral vascular

resistance

12. Inflammatory: - hsCRP, cytokines

13. Nutritional: - albumin

- lipid spectrum

14. Cost/ effectiveness of PD

Study description

Background summary

Chronic heart failure is a serious invalidating condition which incidence increases substantially. Psychosocial burden and medical costs are high. Medical therapy has improved but the limits are obvious. Peritoneal dialysis is promising to make remarkable improvements in the invalidating symptoms and in improving quality of life. It is possible that medical therapy on top of peritoneal dialysis can be intensified and therewith contributes to a furhter quality of life improvement.
Randomized studies are lacking, there are no systematic observations and we do not know to what extent peritoneal dialysis should be offered to patients with chronic heart failure.

Study objective

To improve symptomatology in severe chronic failure patients.

Study design

Multicentre Open, parallel.
Comparing 2 schemes of peritoneal dialysis with Extraneal with standard medical therapy

Intervention

Peritoneal dialysis with Extraneal.

Study burden and risks

The burden of the illness-related symptoms in view of the poor prognosis is high. Several events may occur due to the undelying condition.

The largest risk related to this study is the operative risk related to the endoscopic-operative placement of the PD-catheter. However, this is a standard procedure in another group of patients, namely those with renal failure who have a comparable or maybe even higher risk profile: they do not only suffer from renal failure, but almost always also from some kind of (sometimes serious) heart failure. The risks that have been observed in that group do exist, but fortunately are not frequent in daily practice. Another risk related to the PD-catheter is the development of peritonitis. In renal insufficient patients this complication almost always can be treated with antibiotics without further complications. Finally, sometimes there is catheter malfunction.

Subjects are also asked to attend the outpatient clinic several times for additional investigations. In all groups these are 5 study days: at baseline, 1, 2, 5, and 8 months. On these days a physical examination and laboratory measurements (serum and 24-hour urine collection) are performed, as well as measurements of extracellular volume with bio-impedance as peripheral vascular resistance with a blood pressure measurement device. Questionnaires are filled in at 0, 2, 5, and 8 months; exact measurements of extracellular volume and renal function are done at 0 and 2 months; a 6-min walk test and echo cardiography are performed at 0 and 8 months. Furthermore subjects are asked to qualify the favorability of their condition daily. In the intervention groups there are 7 extra outpatient visits for control; these visits are simple (15 min) and follow the normal procedure and frequency as PD treatment in patients with renal insufficiency.

It can be expected that the burden is acceptable in view of the (clinically significant) improvement in symptoms and decrease in (number / lengths) of hospitalizations. Moreover, patients who are not within the trial will also

have frequent outpatients visits to control for their invalidating condition.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with refractory congestive heart failure, class 3-4:
1. Age > 18 years.
2. Refractory Left Ventricular Congestive Heart Failure: LVEF < 30%.
3. Diminished renal function: eGFR < 60 ml/min, as mean of the last three measurements.
4. Clinically volume overloaded: dyspnoea NYHA III-IV, edema, and/or ascites
5. Chronic CHF during the last 6 months despite evaluation and optimalization by a cardiologist.
6. Patient is on optimal cardiologic medical therapy, which has been stable for more than 4 weeks.

7. Suitable for PD.

Exclusion criteria

1. Hypotension (SBP < 100 mmHg / MAP < 70 mmHg).
2. Instable AP or an elevated troponine-I level > 0,4 ug/l within the last 3 months or > 1 ug/l within the last 6 months.
3. Contraindications for PD (e.g. visual handicap, social).
4. Liver failure.
5. COPD Gold class IV.
6. Malignancy with life expectancy < 2 years.
7. Non compliance.
8. No informed consent.
9. Poor mental health.

Study design

Design

Study phase:	3
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):	02-06-2010
Enrollment:	45
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Extraneal
Generic name:	icodextrin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	05-02-2010
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	23-02-2010
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	01-02-2011
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	14-02-2012
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	18-09-2012
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	11-11-2013
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
EudraCT	EUCTR2009-017711-15-NL
ClinicalTrials.gov	NCT01124227
CCMO	NL29197.099.09