

Is peritoneal dialysis a better treatment for patients with treatment - resistant congestive heart failure?

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Compare usual care in patients with treatment resistant heart failure with additional ultrafiltration by peritoneal dialysis.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON36712

Source

ToetsingOnline

Brief title

PDHF

Condition

- Heart failures
- Renal disorders (excl nephropathies)

Synonym

cardiac failure, heart failure

Research involving

Human

Sponsors and support

Primary sponsor: Nefrologie

Source(s) of monetary or material Support: Ministerie van OC&W, Baxter, subsidie farmacie; unrestricted grant

Intervention

Keyword: congestive heart failure, peritoneal dialysis, treatment resistant

Outcome measures

Primary outcome

Hospitalization days

Secondary outcome

Mortality

Quality of life

Cardiac function

Residual renal function and urine production

Nutrition

Study description

Background summary

The prevalence of end-stage heart failure with recurrent hospitalizations is rising. The possibility of ultrafiltration by peritoneal dialysis will be studied in this study. We compare standard pharmacological treatment with nocturnal peritoneal dialysis as an additional treatment in treatment-resistant patients with congestive heart failure. We suppose the last treatment is superior on hospitalization rate, quality of life and survival.

Study objective

Compare usual care in patients with treatment resistant heart failure with additional ultrafiltration by peritoneal dialysis.

Study design

Prospective multicentre randomised trial.

Intervention

group I standard pharmacological treatment
group II additional nocturnal peritoneal dialysis

Study burden and risks

Group 1: standard care

Group 2: placement of peritoneal dialysis catheter. After training, start peritoneal dialysis with an overnight exchange

Visits: every six weeks, within the regular visits.

Bloodsamples: every six weeks

During visits:

- every 3 months: Quality of life questionnaire, 24-urine analysis, hand grip dynamometry
- every six months: 6 minute walking test, echocardiogram: 1 extra / year

Risk's

Patients in group 1 get the standard treatment, no extra risk's.

Patients in group 2

a. Operation risk. Low due to the small operation.

b. Catheter related complications:

- Obstipation, pericatheter leakage (1-20%), cuff extrusion (3-15%), abdominal wall herniation (<0,1%)

- exit site infection and bacterial peritonitis (1 per 2 patient years)

Contacts

Public

Selecteer

De Boelelaan 1117

1081 HV

NL

Scientific

Selecteer

De Boelelaan 1117

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Severe refractory congestive heart failure with signs of diuretic resistance which is defined as the inability to preserve euvolemia despite maximal diuretic therapy
- Dyspnoea NYHA class III and IV
- Not fit for resynchronisation therapy or patients with relapse of diuretic resistance after resynchronisation therapy
- Age at least 18 years.
- Capable of giving informed consent.

Exclusion criteria

1. Fit for resynchronisation therapy
2. On the heart transplant waiting list
3. Contraindications for peritoneal dialysis: history of multiple abdominal operations
4. MDRD < 10 or > 30 ml/min
5. Severe comorbidity with life expectancy less than 1 year

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Will not start
Start date (anticipated):	01-01-2011
Enrollment:	45
Type:	Anticipated

Ethics review

Approved WMO	
Date:	18-02-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL31323.029.10