The effect of intradialytic parenteral nutrition on nutritional status and quality of life in hemodialysis patients

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The aim is to see whether intradialytic parenteral nutrition is an efective treatment against the loss of muscle mass

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52472

Source
ToetsingOnline

Brief title
IDPN - Study

Condition

- Other condition
- Appetite and general nutritional disorders
- Renal disorders (excl nephropathies)

Synonym
malnutrition, sarcopenia

Health condition

dialyse

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Baxter,Subsidie ontvangen vanuit Bacter B.V.

Intervention

Keyword: intradialytic parenteral nutrition, Nutritional Status, Quality of Life

Outcome measures

Primary outcome

To analyze the change in lean tissue Mass (LTM) assessed by Body Composition

Monitor (BCM).

Secondary outcome

To analyze the change in:

- Adipose Tissue Mass (ATM) assessed by Body Composition Monitior (BCM)

- Body weight

- Target weight

- Functionality assessed by hand grip strenght (HGS)

- Appetite (NRS)

- Muscle health index assessed by ultrasound

- Subjective Global Assessment (SGA), 7 point scale

- Food intake assessed by 24-hours recall with global dietary history (calories

and protein)

- Exercise, assessed by Activ8 and exercise dairy

- Quality of Life: assessed by KDQoL and PANAS

- KT/V

- (n)PCR

- Serum CRP

- Serum albumin

- Serum pre-albumin

- Serum bicarbonate

- Phase Angel, assessed by Body Composition Monitor (BCM)

• Changes in hormones

• Hospital admission

Study description

Background summary

Hemodialysis is a life-saving treatment but has a major impact on health including on nutritional status. Nutritional status and body composition are closely linked to morbidity, mortality and quality of life (1-3). Muscle mass appears to be the best read-out for the association between nutritional status and outcomes(4-12). Protein-energy wasting (PEW) is the term to describe the state of decreased body stores of protein and energy fuels (body protein and fat masses) in chronic kidney disease(13, 14), this is a hypercatabolic state leading to muscle wasting (sarcopenia) and cachexia (1). PEW comes in from 20 to 70% in chronic hemodialysis patients, with a mean of 40%(13, 14).
Thus, a sarcopenia-correcting intervention in hemodialysis patients has the potential to improve quality of life. Intradialytic parenteral nutrition (IDPN) is a nutritional support therapy that is directly administered into the bloodstream during the hemodialysis session. A study using labeled isotopes showed that IDPN may represent a sarcopenia-correcting intervention, because it reversed patients from a state of catabolism to a state of protein synthesis, especially in muscle(15). However, there is equipoise as to whether IDPN improves nutritional status and quality of life in hemodialysis patients. This is related to the fact that most studies are limited in experimental design(16). Two prospective studies showed that IDPN increased pre-albumin (a biochemical marker of nutritional status), but showed no survival benefit, although the studies were likely underpowered to address this endpoint(17, 18).
In a recently completed study we observed that all hemodialysis patients lose muscle mass during follow-up (3.8 kg in 12 weeks, Figure 1). In a small pilot study, we observed that IDPN can reduce this muscle wasting by a factor >2.5.

Based on our preliminary data, we propose a 3-month double-blind and placebo-controlled clinical trial of IDPN in hemodialysis patients with muscle mass as primary endpoint and quality of life as secondary endpoint.

Study objective

The aim is to see whether intradialytic parenteral nutrition is an efective treatment against the loss of muscle mass

Study design

The study has the following characteristics:
• Multi-center
• Double-blind
• Randomized
• Placebo controlled

The duration of the study: 4 months; 3 months intervention and 1 month follow-up.
The setting of the study is: hemodialysis unit of a university hospital.

Intervention

Intradialytic parenteral nutrition

Study burden and risks

The measurements will be performed during a dialysis session when patients are already in the hospital. Additional efforts required from participants include wearing the activity monitor, keeping an activity diary,and filling out the questionnaires during dialysis. The risks of study participation are the increased ultrafiltration volume and other potential side-effects of IDPN. These risks are limited by close monitoring of overhydration (using the BCM), blood pressure, body weight, blood volume measurements, and laboratory tests (e.g., blood glucose and liver enzymes). The potential benefit of the study are the sarcopenia-correcting effects of the intradialytic parenteral nutrition.

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

- Age: >= 18 years
- Hemodialysis, 3 times / week, minimum 3,5 hours / session.

Exclusion criteria

- Life expectancy < 6 months
- Planned kidney transplant within 4 months
- Active treatment for infection
- Pregnancy
- Parenteral nutrition for at least four weeks prior to screening
- Unipolar pacemaker with a very low sensitivity threshold
- Regular exclusion criteria for the use of parenteral nutrition in hemodialysis patients

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	16-09-2019
Enrollment:	166
Type:	Actual

Medical products/devices used

Generic name:	Software MuscleSound
Registration:	No

Ethics review

Approved WMO Date:	19-11-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-12-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-09-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	06-11-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-01-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2018-003899-13-NL
CCMO	NL65803.078.18