The effects of protein ingestion and exercise on plasma and dialysate amino acid concentrations during hemodialysis

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To assess the effects of intradialytic exercise and protein ingestion on amino acid loss into the dialysate and plasma total amino acid concentrations.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON48888

Source
ToetsingOnline

Brief title
Intradialytic protein ingestion and exercise study (IPES)

Condition

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

Synonym
Amino acid loss during hemodialysis, hemodialysis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Amino Acids, Exercise, Hemodialysis, Protein

Outcome measures

Primary outcome

Primary study parameters are amino acid loss into the dialysate and plasma

total amino acid concentrations.

Secondary outcome

Secondary study parameters are the loss of essential amino acids into the

dialysate, plasma essential amino acid, glucose, and insulin concentrations,

interstitial glucose concentrations, and changes in blood pressure.

Study description

Background summary

Chronic hemodialysis patients suffer from poor physical functioning due to progressive loss of skeletal muscle mass and function. Preliminary data from our lab shows that 8 - 15 grams of amino acids are lost into the dialysate during a hemodialysis session, causing a significant decline in plasma amino acid concentrations. Few studies in chronic hemodialysis patients suggest that oral protein ingestion during hemodialysis is able to prevent this decline and associated muscle protein breakdown. However, the amount of protein required to achieve this effect (±60 g) is not feasible for clinical practice. Nonetheless, a feasible amount of protein combined with an additional anabolic stimulus, such as exercise, might be able to prevent the hemodialysis-induced decline in plasma amino acid concentrations. In healthy adults, exercise before protein ingestion enhances the net protein balance of skeletal muscle and improves postprandial glycemia. However, the effect of intradialytic exercise on plasma and dialysate amino acid concentrations throughout hemodialysis is unclear. In addition, it is not known if this effect differs between fed and fasted patients. Knowledge about the acute metabolic response after protein ingestion and exercise during hemodialysis is important for the development of intradialytic anabolic strategies in chronic hemodialysis patients.

Study objective

To assess the effects of intradialytic exercise and protein ingestion on amino acid loss into the dialysate and plasma total amino acid concentrations.

Study design

Randomized cross-over (four groups) study design.

Intervention

During four HD sessions, patients will (A) ingest a placebo drink, (B) ingest a placebo drink and perform aerobic exercise, (C) ingest a protein supplement, and (D) ingest a protein supplement and perform aerobic exercise. Following initiation of the hemodialysis session, arterial plasma samples will be obtained with 30-min intervals during a 4 h period for analysis of plasma amino acid, glucose, and insulin concentrations. In addition, spent dialysate will be collected and glucose monitoring will be applied continuously throughout the hemodialysis session.

Study burden and risks

The risks involved in participating in this experiment are minimal. Blood and spent dialysate samples will be collected from the arterial blood line and dialysate line, respectively, without extra burden or risk for the patients. Oral food intake during hemodialysis is routine for most patients and is well tolerated. The protein supplements are produced according to HACCP standards and are safe for human use. Intradialytic exercise is common practice in many hemodialysis departments, and (serious) adverse events are rarely reported.

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

- Aged >18 years
- Ability to provide written informed consent
- Hemodialysis treatment for >3 months
- Well-functioning arteriovenous shunt in upper or lower arm

Exclusion criteria

- Unstable cardiac status (i.e. cardiac ischemia)
- Physical limitations affecting usage of the bike
- Poor blood sugar control
- Active infection or illness
- Poorly functioning shunt
- Previous episodes of intradialytic hypotension related to food intake
- Hospitalization <3 months prior to study period
- Missed hemodialysis session <1 month prior to study period
- Allergies to milk protein

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-01-2019
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO Date:	14-08-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-10-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL65880.068.18