Intradialytic protein ingestion and exercise study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27277

Source
Nationaal Trial Register

Brief title
IPES

Health condition

Hemodialyse Hemodialysis
Fysieke inspanning Exercise
Eiwit Protein
Aminozuren Amino Acids

Sponsors and support

Primary sponsor: Maastricht University Medical Centre+
Source(s) of monetary or material Support: Maastricht University Medical Centre+

Intervention

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 acids, glucose, and insulin concentrations, interstitial glucose concentrations, plasma and spent dialysate uremic toxin 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. 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. Therefore, the present study assess the effects of intradialytic exercise and protein ingestion on amino acid loss into the dialysate and plasma total amino acid concentrations.

Study objective

- Intradialytic protein ingestion increases plasma total amino acid concentrations throughout hemodialysis compared to placebo.

- Intradialytic exercise increases amino acid loss into the dialysate in fasted patients and decreases amino acid loss when performed before protein ingestion.

Study design

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.

Intervention

During four hemodialysis 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.

Contacts

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Eligibility criteria

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:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2018
Enrollment:	10
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-07-2018
Application type:	First submission

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
NTR-new	NL7152
NTR-old	NTR7351
Other	18-3-022 : METC

Study results

Summary results
The results of this investigation will be published in a high-impact, scientific journal, regardless of the outcome of this study.