

Intradialytic protein ingestion and exercise study

Gepubliceerd: 10-07-2018 Laatste bijgewerkt: 18-08-2022

- 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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27277

Bron

Nationaal Trial Register

Verkorte titel

IPES

Aandoening

Hemodialyse Hemodialysis
Fysieke inspanning Exercise
Eiwit Protein
Aminozuren Amino Acids

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre+

Overige ondersteuning: Maastricht University Medical Centre+

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

- 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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2018
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 10-07-2018

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7152
NTR-old	NTR7351
Ander register	18-3-022 : METC

Resultaten

Samenvatting resultaten

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