

Ketoacids during hemodialysis

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Co-ingesting keto-analogues of branched-chain AAs along with protein during HD attenuates HD-initiated muscle catabolism.

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

Samenvatting

ID

NL-OMON26423

Bron

Nationaal Trial Register

Verkorte titel

KIC-HD

Aandoening

End-stage renal disease

Ondersteuning

Primaire sponsor: Maastricht University

Overige ondersteuning: Maastricht University

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint in this study will be the net AA balance over the forearm, calculated by subtracting the venous from arterial AA concentrations.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: End-stage renal disease patients on hemodialysis (HD) generally show a rapid decline in muscle mass and strength. Hemodialysis itself is considered an important cause of this decline in nutritional status, as it removes small-sized nutrients, such as amino acids (AAs), from the circulation. Previously, we have shown that the continuous removal of AAs during HD results in significantly decrease plasma AAs concentrations, which increase muscle proteolysis. In addition, we have shown that ingestion of 40 g protein during HD is able to compensate for AA removal. However, due to early satiety and the high nitrogen and phosphate content of protein, this strategy is not feasible for all hemodialysis patients. We have previously shown that ingestion of ketoanalogues of AAs (ketoacids), which do not contain nitrogen or phosphate, increases muscle protein synthesis rates. Currently it is, to our knowledge, not known if ketoacid ingestion during HD could support muscle maintenance.

Objective: To assess whether co-ingesting keto-analogues of branched-chain AAs along with protein during HD can attenuate HD-initiated muscle catabolism.

Study design: Randomized cross-over (two treatments) design.

Study population: 12 chronic HD patients

Intervention: During two HD sessions, included patients will ingest sips of (1) a protein beverage and (2) a protein and ketoacid beverage. Throughout the HD session, arterial and venous plasma samples and breath samples will be obtained at regular intervals. In addition, spent dialysate will be collected continuously throughout the hemodialysis session.

Main study parameters/endpoints: The primary endpoint in this study will be the net AA balance over the forearm, calculated by subtracting the venous from arterial AA concentrations. Secondary study parameters include plasma and breath L-(ring-13C6)-phenylalanine enrichments and AA concentrations in spent dialysate.

Doel van het onderzoek

Co-ingesting keto-analogues of branched-chain AAs along with protein during HD attenuates HD-initiated muscle catabolism.

Onderzoeksopzet

Samples will be taken every 30 min throughout 2 hemodialysis sessions

Onderzoeksproduct en/of interventie

During two HD sessions, included patients will ingest sips of (1) a protein beverage and (2) a protein and ketoacid beverage. Throughout the HD session, arterial and venous plasma samples and breath samples will be obtained at regular intervals. In addition, spent dialysate will be collected continuously throughout the hemodialysis session.

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)

- Hospitalization <1 months prior to study period
- Missed hemodialysis procedure <1 month prior to study period
- Active inflammatory disease / malignancies
- Uncontrolled hypertension (>200/100mm Hg) or arrhythmia
- Previous episodes of intradialytic hypotension related to food intake
- Allergies to milk proteins
- Dysphagia
- Pregnancy
- Cognitive disorders

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	22-03-2021
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies	
Datum:	26-02-2021
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	NL9296
Ander register	METC AzM/UM : METC 20-108

Resultaten