Ketoacids during hemodialysis

No registrations found.

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

Summary

ID

NL-OMON26423

Source Nationaal Trial Register

Brief title KIC-HD

Health condition

End-stage renal disease

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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 outcome

Secondary study parameters include plasma and breath L-(ring-13C6)-phenylalanine enrichments and AA concentrations in spent dialysate.

1 - Ketoacids during hemodialysis 26-06-2025

Study description

Background summary

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 know 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.

Study objective

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

Study design

Samples will be taken every 30 min throughout 2 hemodialysis sessions

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.

Contacts

Public

Maastricht University Medical Centre+ / NUTRIM School of Nutrition and Translational Research in Metabolism / Department of Human Biology Floris Hendriks

0655522347

Scientific

Maastricht University Medical Centre+ / NUTRIM School of Nutrition and Translational Research in Metabolism / Department of Human Biology Floris Hendriks

0655522347

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

- 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

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):	22-03-2021
Enrollment:	10
Туре:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	26-02-2021
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	NL9296
Other	METC AzM/UM : METC 20-108

Study results