The effect of parenteral nutrition during nighttime versus daytime on bone turnover and energy metabolism in intestinal failure patients.

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This study aims to determine the effect of nocturnal versus daytime cyclic infusion of parenteral nutrition in adult chronic intestinal failure patients on bone turnover, glucose metabolism, nitrogen balance, sleep and wake rhythm and clock genes...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51527

Source
ToetsingOnline

Brief title
NutriSync

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)
- Bone, calcium, magnesium and phosphorus metabolism disorders

Synonym
Circadian synchronisation, energy metabolism

Health condition

sleep - wake rhythm, nitrogen balance and clock gene expression

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,NWO Doctoral Grant for Teachers round 2021-II 023.018.051

Intervention

Keyword: Bone turnover, Clock gene expression, Glucose metabolism, Parenteral Nutrition

Outcome measures

Primary outcome

Differences in the bone turnover markers serum P1NP and CTX-1, changes in

glucose variability measured by a continuous glucose monitor and changes in

insulin levels.

Secondary outcome

Differences in nitrogen balance, sleep/wake rhythm, clock gene expression,

resting energy expenditure and substrate oxidation rates, body temperature

Study description

Background summary

Many chronic intestinal failure patients are on cyclic infusion of parenteral nutrition during the nighttime for practical reasons, but this pattern of feeding is not concordant with their biological clock. Nocturnal parenteral nutrition may negatively affect bone turnover, nitrogen balance, sleep/wake rhythms and glucose metabolism. Diurnal administration of parenteral nutrition is expected to be more in line with the biological clock and can possibly lead to fewer complications due to circadian desynchronization.

Study objective

This study aims to determine the effect of nocturnal versus daytime cyclic

infusion of parenteral nutrition in adult chronic intestinal failure patients on bone turnover, glucose metabolism, nitrogen balance, sleep and wake rhythm and clock genes expression.

Study design

We will conduct a randomized crossover pilot study

Intervention

patients will receive nocturnal parenteral nutrition for 1 week (period A) and will switch to diurnal parenteral nutrition (period B) for 1 week. At the start of the study, patients will be randomly assigned to study period A or B and will cross over after the first study period. After both study periods, patients will be admitted to the metabolic unit for 24 hours to measure bone turnover markers, nitrogen balance, glucose variability, glucoregulatory hormones, energy expenditure and substrate oxidation rates and clock gene expression in leukocytes.

Study burden and risks

patients will wear an actigraph and a continuous glucose monitor for 14 days (2 study periods). They will report their sleep quality and oral intake during both study periods. Patients will be admitted to the metabolic unit twice for 24-hous. They will undergo blood sampling 6 times, (resting) energy expenditure and substrate oxidation rates measurements 6 times and will wear multiple i-buttons for measuring body temperature. They are asked to sample their urine and faeces output for 24-hours.
All risks related to the presence of the central venous catheter and the use of parenteral nutrition are pre-existing risks associated with the underlying disease. We do ask patients to switch temporally to diurnal parenteral nutrition, which can have impact on their daily routine for a maximum of 1 week. Placing a cannula for blood sampling can be an unpleasant experience for the patients. There is a low risk of phlebitis; this is unpleasant, but not harmful, of temporary nature and self-limiting.

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

Chronic intestinal failure
Parenteral nutrition for at least 3 nights a week
Parenteral nutrition for more than 1 year
No major changes in parenteral nutrition for 3 months prior to inclusion

Exclusion criteria

Parenteral infusion for more than 16 h a day
Use of bone modifying drugs in the last 2 years
Bone fractures in the past year
Renal insufficiency (eGFR < 30 ml/min)
HbA1c >=53 mmol/ml
Use of corticosteroids (systemic, cutaneous >5cm2 or WHO class I-III)
Shift work
Performing intensive exercise (> 2 hours a day and > 3 times a week)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-07-2023
Enrollment:	20
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	24-02-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-07-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL82280.018.22