Continu versus intermitterend voeden op de intensive care kinderen

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Intermittent versus continuous enteral feeding is feasible and safe in critically ill children, and intermittent feeding will lead to a fasting response with an increased ketosis, which could potentially activate autophagy while providing sufficient...

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Fatale aflopen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22860

Bron
Nationaal Trial Register

Verkorte titel
ContInNuPIC

Aandoening

- Fatale aflopen

Aandoening

All health conditions requiring admittance to the intensive care unit

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor:	European Society for Clinical Nutrition and Metabolism
Secundaire sponsoren:	Sophia Research Foundation
Overige ondersteuning:	Nova Biomedical

Onderzoeksproduct en/of interventie

- Voedingsstoffen/Voedingsmiddelen

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome of the proof-of-concept study will be the feasibility (ketogeneic response, nutritional intake, enteral tolerance) and safety (glycaemic control, gastro-intestinal complications) of a daily feeding and fasting cycle in critically ill children of different age-groups while providing equal amounts of daily nutrients as with standard continuous feeding.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Withholding Parenteral Nutrition during the first week of critical illness, as compared with an early start (<48 hours), reduced length of intensive care dependency and the number of nosocomial infections. The benefit of this counterintuitive nutritional strategy, through which low macronutrient intakes were accepted, is presumed to be caused by activation of autophagy due to a fasting response with increased ketosis. Autophagy is an intracellular recycling process crucial for maintaining cellular integrity and function. Its protective role against various forms of critical illness induced organ failure, including ICU acquired muscle weakness, is strongly activated during periods of fasting. Currently, artificial feeding is usually administered through continuous infusion, although solid evidence supporting this practice is lacking. Intermittent, as compared with continuous, (par)enteral nutrition may provide a more physiological feeding/fasting pattern which activates autophagy, while providing sufficient nutrition during critical illness. Such a physiological feeding/fasting pattern could also sustain circadian rhythm and influence pharmacodynamics and kinetics in critically ill children. Objective: The main research objectives for the proof-of-concept study are to show the feasibility and safety of a daily cycle of feeding and fasting in critically ill children of different age-groups, that will trigger an adequate fasting response while providing equal amounts of daily nutrients as with standard continuous (24hrs) feeding. Study design: A randomized non-blinded proof-of-concept study to explore the feasibility and safety of intermittent feeding in 140 critically ill children stratified over three age groups; neonates (≤28d), infants (<1yr) and children (≥1yr) while overall providing sufficient amounts of daily nutrients as with standard continuous feeding. The study intervention will last a maximum of 14 days or until PICU discharge, or the ability for “oral nutrition”, whichever comes first.

Doel van het onderzoek

Intermittent versus continuous enteral feeding is feasible and safe in critically ill children, and intermittent feeding will lead to a fasting response with an increased ketosis, which could potentially activate autophagy while providing sufficient nutrition.

Onderzoeksopzet

PICU admission

Onderzoeksproduct en/of interventie

intermitterend voeden met een nachtelijke vastenperiode

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Leeftijd
Pasgeborenen
Pasgeborenen
Baby's en peuters (28 dagen - 23 maanden)
Baby's en peuters (28 dagen - 23 maanden)
Kinderen (2-11 jaar)
Kinderen (2-11 jaar)
Adolescenten (12-15 jaar)
Adolescenten (12-15 jaar)

Adolescenten (16-17 jaar)
Adolescenten (16-17 jaar)

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Kritiek zieke kinderen (aterm geboren - 18 jaar oud), met verwachte opnameduur van 2 dagen of meer, verwacht afhankelijk te worden/zijn van kunstmatige voeding (sondevoeding of voeding via het infuus)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- mogelijkheid tot orale intake

- niet reanimeren beleid

- verwacht overlijden binnen 24u

- heropname na eerdere deelname

- transfer vanaf andere kinder IC meer dan 3 dagen of daar al voeding gehad

- ketoacidose/hyperosmolair coma

- metabole aandoening waarvoor speciaal dieet gevolgd wordt of contra-indicatie voor (intermitterend) voeden

- premature leeftijd (<37 weken postmenstruale leeftijd)

- short bowel syndroom of andere aandoening waardoor reeds infuusvoeding nodig is

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	19-05-2020
Aantal proefpersonen:	140
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

Ethische beoordeling

Goedgekeurd WMO

Datum:	11-02-2020
Soort:	Eerste indiening
Toetsingscommissie:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48138
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7877
CCMO	NL70184.000.19
OMON	NL-OMON48138

Resultaten

Datum resultaten gemeld: 17-07-2023

Totaal aantal deelnemers: 140

Samenvatting resultaten
Between May 19, 2020, and July 13, 2022, 140 critically ill children, median (first quartile; third quartile) age 0.3 (0.1; 2.7) years, were randomised to intermittent (n=67) or continuous feeding (n=73). In the intermittent feeding group, BHB levels were significantly higher (median 0.4 (0.2; 1.0) vs. 0.3 (0.1; 0.7) mmol/L, p<0.001). The ratio of total caloric intake in the intermittent feeding group to the intake in the continuous feeding group was not consistently significantly more than 0.67, thus not proving non-inferiority. No severe, resistant hypoglycaemic events, nor severe gastrointestinal complications related to the intervention occurred, and feeding intolerance did not occur more often in the intermittent than in the continuous feeding group.

Karakteristieken onderzoekspopulatie
Median (first quartile (Q1); third quartile (Q3)) age was 0.4 years (0.1; 3.1 years) vs. 0.3 years (0.1; 2.3 years), and median Paediatric Index of Mortality 3 (PIM3)(28) score -3.4 (-4.5; -2.5) vs. -3.9 (-4.5; -2.5) in the intermittent vs. the continuous

Deelnemers doorstroom
Between May 19, 2020, and July 13, 2022, 140 critically ill children were included in the study; 67 were randomised to the intermittent and 73 to the continuous feeding group.

Ongewenste voorvallen
Serious adverse events (SAEs) included the caecum perforation mentioned above (intermittent feeding group), a rupture of the vena jugularis during an attempt for extracorporeal membrane oxygenation (intermittent feeding group), one event of severe bradyca

Onderzoeksvariabelen / uitkomstmaten
"In the intermittent feeding group, BHB levels were significantly higher than in the continuous feeding group (median (Q1; Q3) 0.4 (0.2; 1.0) vs 0.3 (0.1; 0.7) mmol/L, p<0.001). Regarding nutritional intake, the lower limit of the 90% CI of the ratio of