Enteral versus parenteral feeding in pediatric oncology patients with gastro-intestinal mucositis

Gepubliceerd: 31-07-2013 Laatst bijgewerkt: 18-08-2022

Which of 2 feeding strategies for children during chemotherapy induced mucositis is optimal for the patient: an elementary diet, containing only simple macronutrients administered via continuous enteral drip; or total parenteral nutrition.

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

Samenvatting

ID

NL-OMON29350

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Child; Cancer; Mucositis; Nutrition

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG), Beatrix Children's Hospital
Overige ondersteuning: Dutch Cancer Society

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

-Nutritional state (weight, length, mid upper arm circumference)

Toelichting onderzoek

Achtergrond van het onderzoek

In this project we will test which of two feeding strategies for children during chemotherapy induced mucositis is optimal, an elementary diet administered via continuous enteral drip, or total parenteral nutrition. The study will compare the two feeding strategies in a randomized crossover design. Children admitted to the UMCG for treatment of AML of B-NHL will be included. Using a crossover design, during two identical chemotherapy courses, each patient will get both the elementary diet and the total parenteral nutrition randomly with the nutritional state as primary outcome.

Doel van het onderzoek

Which of 2 feeding strategies for children during chemotherapy induced mucositis is optimal for the patient: an elementary diet, containing only simple macronutrients administered via continuous enteral drip; or total parenteral nutrition.

Onderzoeksopzet

- Nutritional state: before start of the chemotherapy course and before start of the next course

- Plasma citrulline: every 2 days until next chemotherapy course

Onderzoeksproduct en/of interventie

Patients will be given standard nutrition(elementary diet administered via continuous enteral drip) or total parenteral nutrition during 2 identical chemotherapy courses. Using a crossover design, each patient will get both the standard diet and the study diet randomly.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children(0-18 years of age) admitted to the University Medical Center Groningen for the treatment of acute myeloid leukemia(AML) or B-Non Hodgkin lymphoma(B-NHL). They receive chemotherapy according to the Dutch Childhood Oncology Group(DCOG), for both AML and B-NHL containing at least 2 identical chemotherapy courses.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Patients and their parents are excluded when they are insufficiently capable of speaking and understanding the Dutch language.

-Patients are excluded when life expectancy is estimated to be below six months.

-No gastric tube in place in children who do eat during their chemotherapy (very rare) are excluded since we do not give a naso-gastric tube only for study purposes.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over

Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-08-2013
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-07-2013
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	NL3937
NTR-old	NTR4099
Ander register	METc : 2013/094
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A