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

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29350

Source
NTR

Brief title
N/A

Health condition

Child; Cancer; Mucositis; Nutrition

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG), Beatrix Children's Hospital
Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- The degree of mucositis measured by plasma citrulline

- Quality of life (using Pedsqual questionnaire every 5 days and daily Cantrills ladder and VAS score)

- Number of infectious complications

- Number of bacteraemias

- Percentage of calculated optimal quantity of tube feeding actually given

- Liver toxicity scores according to NCI-CTCAE version 4.0

- Length of hospital stay

- Clinical symptoms of mucositis (NCI-CTCAE 4.0)

Study description

Background summary

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.

Study objective

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.

Study design

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

- Plasma citrulline: every 2 days until next chemotherapy course

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

-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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-08-2013
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-07-2013
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	NL3937
NTR-old	NTR4099
Other	METc : 2013/094
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A