

Protection against chemotherapy induced damage in the digestive tract in childhood cancer patients.

No registrations found.

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

Summary

ID

NL-OMON23956

Source

NTR

Brief title

N/A

Sponsors and support

Primary sponsor: Numico Research

Intervention

Outcome measures

Primary outcome

Gastro-intestinal toxicity such as:

1. Mucositis;
2. Diarrhoea;
3. Intestinal permeability;

Safety:

4. Renal function;

5. Serum TGF-beta2.

Secondary outcome

N/A

Study description

Background summary

Patients receive investigation product during one course of chemotherapy and control placebo during the other similar course. Order of administration is determined by randomisation.

During and after the chemotherapy course different parameters of gastro-intestinal toxicity and safety are determined.

Study objective

1. TGF-beta protects childhood cancer patients against chemotherapy induced damage in the digestive tract;

2. TGF-beta can safely be administered to childhood cancer patients.

Study design

N/A

Intervention

Nutritional supplement TGF-beta2 is added to (tube) feeding and compared to placebo during two similar courses of chemotherapy in a randomised, double-blind crossover design.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children with ANLL, MDS, B-NHL, infant ALL who will receive 2 or more similar courses of chemotherapy;
2. Children diagnosed with other malignancies who receive more than 2 similar courses of chemotherapy and develop mucosal barrier injury during one of the first courses;
3. Age 0-18 years;
4. Informed consent.

Exclusion criteria

1. Clinical signs of inflammatory bowel disease, coeliac disease or cow's milk protein allergy;
2. Radiotherapy of the abdomen less than 6 months before TGF-beta2 administration.

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):	01-01-2001
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion	
Date:	13-09-2005
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	NL362

Register

NTR-old

Other

ISRCTN

ID

NTR401

: N/A

ISRCTN13358395

Study results

Summary results

1. Pediatr Blood Cancer. 2007 May;48(5):532-9.