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

Submission date 27/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/01/2006	**Overall study status** Completed	
Last Edited 04/11/2008	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR401

Study information

Scientific Title

Study objectives
1. Transforming growth factor beta (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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised, double-blind placebo controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Chemotherapy induced damage in the digestive tract

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

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Transforming growth factor beta (TGF-beta)

Primary outcome measure
Gastrointestinal toxicity such as:
1. Mucositis
2. Diarrhoea
3. Intestinal permeability

Safety:
1. Renal function
2. Serum TGF-beta

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2001

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Children with acute non-lymphocytic leukaemia (ANLL), myelodysplastic syndromes (MDS), B-cell non-hodgkin's lymphoma (B-NHL), infant acute lymphoblastic leukaemia (ALL) who will receive two or more similar courses of chemotherapy
2. Children diagnosed with other malignancies who receive more than two similar courses of chemotherapy and develop mucosal barrier injury during one of the first courses
3. Aged 0 - 18 years
4. Informed consent

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
30

Key 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-beta administration

Date of first enrolment
01/01/2001

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3015 GJ

Sponsor information

Organisation
Danone Research B.V. (The Netherlands)

Sponsor details
P.O. Box 7005
Wageningen
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Sponsor type
Industry

ROR
https://ror.org/01c5aqt35

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration