

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

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/11/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

Netherlands

6700 CA

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