Typhlitis study.

No registrations found.

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

Summary

ID

NL-OMON21843

Source
NTR

Brief title
Typhlitis in AML

Health condition

Acute myeloid leukemia
Acute myeloide leukemie

Sponsors and support

Primary sponsor: Prof.dr. E. Vellenga
Dept. of Hematology
University Medical Center Groningen
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Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

1. Defining the severity of epithelial dysfunction measured with mucositis score, the stool volume, the calprotectin level in the stool, the urinary Cr EDTA excretion and serum IL-8 and CRP levels;

2. Typhlitis based on clinical symptomatology and CT-scanning abdomen.

Secondary outcome

Before and after treatment with chemo different parameters will be examined.

Study description

Background summary

Rationale:

10-20% of the patients with acute myeloid leukaemia (AML) develop typhlitis following intensive chemotherapy. This might be related to cytotoxic effects of chemotherapy to epithelial and endothelial cells. So far no predictive parameters have been identified that can recognize this subgroup of patients.

Objective:

To identify predictive parameters for typhlitis in AML patients treated with intensive chemotherapy.

Study design:

Pilot study. AML patients that have been treated with intensive chemotherapy will be followed during 14-days following chemotherapy regarding parameters that reflect epithelial damage.

Study population:

1. Patient age 18-70 years;

2. Treated for AML with intensive chemotherapy.

Intervention:

1. Blood and stool samples will be collected;

2. CT-scan of abdomen at day 10-12;

3. Mucositis score will be determined;

4. DNA isolation from normal peripheral blood.

Main study parameters/endpoints:

1. Defining the severity of epithelial dysfunction measured with mucositis score, the stool volume, the calprotectin level in the stool, the urinary Cr EDTA excretion and serum IL-8 and CRP levels;

2. Typhlitis based on clinical symptomatology and CT-scanning abdomen.

Procedure:

1. Sampling blood and stool;

2. CT-scan.

Investigations:

1. Mucositis score; stool volume;

2. Serum IL-8 and CRP levels;

3. Urinary excretion of;

4. CT-scan abdomen;

5. DNA isolation from normal peripheral blood.

Country of recruitment:

The Netherlands.

Study objective

N/A

Study design

N/A

Intervention

1. Blood and stool samples will be collected;

2. CT-scan of abdomen at day 10-12;

3. Mucositis score will be determined;

4. DNA isolation from normal peripheral blood.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18-70 years;

2. Diagnosed with AML and treated with intensive chemotherapy.

Exclusion criteria

Ineligible to perform the tests.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2008
Enrollment:	45
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-05-2009
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	NL692
NTR-old	NTR1800
Other	MEC UMCG : 2008/113
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A