Identification of predictive parameters for typhlitis in AML patients treated with intensive chemotherapy

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Leukaemias
Study type	Observational non invasive

Summary

ID

NL-OMON31938

Source
ToetsingOnline

Brief title
Typhlitis in AML

Condition

- Leukaemias

Synonym
AML; leukemia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: AML, infections

Outcome measures

Primary outcome

- 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.

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

- DNA isolation from normal peripheral blood cells for determining polymorphism

of metabolism genes.

Secondary outcome

Not applicable.

Study description

Background summary

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.

Study 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 burden and risks

Intervention
- Blood and stool samples will be collected
- Echography of abdomen at day 10-12
- Mucositis score will be determined
- DNA isolation from normal peripheral blood

Procedure
- Sampling blood and stool
- Echography

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- age 18-70 years
- patients with AML treated with intensive chemotherapy

Exclusion criteria

Ineligible to perform the proposed tests.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2010
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL23201.042.08