Identification of predictive parameters for 6-MP response in AML patients

Published: 04-12-2008
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To determine predictive parameters for AML patients responsive on 6-MP treatment and to correlate response with changes in lymphocyte subpopulations.

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

Summary

ID

NL-OMON31997

Source
ToetsingOnline

Brief title
Prognostic parameters for 6-MP treatment

Condition

- Leukaemias

Synonym
AML; treatment

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: 6-MP, AML

Outcome measures

Primary outcome

- AML blasts cells will be analyzed for the expression of drug-resistant

parameters, nuclear receptor and the in vitro responsiveness to 6-MP.

- Facs analyses will be performed to define the changes in lymphoid markers

during treatment of 6-MP.

- Treatment response of patients will be defined by improvements in peripheral

blood cell counts and bone marrow composition.

Secondary outcome

Not applicable

Study description

Background summary

30%-40% of the patients with acute myeloid leukemia (AML) demonstrate a clinical response upon treatment with 6-mercaptopurine (6-MP). So far no predictive parameters have been identified that recognize this subgroup of patients, but preliminary data suggest an immunological mediated effect that might be operative in addition to a cytostatic effect.

Study objective

To determine predictive parameters for AML patients responsive on 6-MP treatment and to correlate response with changes in lymphocyte subpopulations.

Study design

Pilot study. AML patients with relapsing disease and/or not eligible for intensive chemotherapy will be treated with 6-MP. Before treatment and during treatment peripheral blood and bone marrow cells will be studied.

Study burden and risks

Additional blood en bone marrow will be collected during regular sampling.

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 years
- diagnosed with (relapsing) AML not eligible for intensive chemotherapy

Exclusion criteria

Ineligible to perform proposed test

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2008
Enrollment:	18
Type:	Anticipated

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	NL23276.042.08