

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

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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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Leukaemias
<b>Study type</b>	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

### **Public**

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9713 GZ Groningen  
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### **Scientific**

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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

CCMO

### ID

NL23276.042.08