

# 6-MP studie.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON28582

### Source

NTR

### Brief title

6-MP in AML

### Health condition

Acute Myeloid leukemia  
Acute myeloide leukemie

## Sponsors and support

**Primary sponsor:** Prof.dr. E. Vellenga

Dept. of Hematologie  
University Medical Center Groningen  
P.O. Box 30.001  
9700 RB Groningen  
The Netherlands

**Source(s) of monetary or material Support:** Not applicable

## Intervention

## Outcome measures

### Primary outcome

1. Expression of multidrug-resistance genes, nuclear receptors and in vitro susceptibility for 6-

MP;

2. Changes in the lymphoid compartment during treatment with 6-MP;

3. HLA-type;

4. Clinical response on treatment with 6-MP.

### **Secondary outcome**

N/A

## **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**

N/A

### **Study design**

N/A

### **Intervention**

Peripheral blood and bone marrow cells will be collected before and during treatment with 6-MP.

## **Contacts**

### **Public**

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## Eligibility criteria

### Inclusion criteria

1. Age >18 years;
2. Diagnosed with (relapsing) AML and not eligible for intensive chemotherapy.

### Exclusion criteria

Ineligible or not willing to perform the proposed tests.

## Study design

### Design

Study type:	Observational non invasive
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: 18  
Type: Anticipated

## Ethics review

Positive opinion  
Date: 07-05-2009  
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	NL1701
NTR-old	NTR1811
Other	UMCG Groningen :
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A