

# TRough vs AUC Monitoring of cyclosporine: A randomized comparison of adverse drug reactions in allogeneic stem cell recipients (TRAM-study)

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The number and severity of adverse drug reactions (renal function, nausea and tremor) of cyclosporine using AUC targeted Therapeutic Drug Monitoring as compared to C0 targeted TDM.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Leukaemias
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON39871

### Source

ToetsingOnline

### Brief title

TRAM study

### Condition

- Leukaemias

### Synonym

allogeneic stemcel transplantation

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Adverse drug reactions, AUC, cyclosporine, TDM

## Outcome measures

### Primary outcome

Adverse drug reactions (headache, tremor, renal dysfunction, hypertension).

Quality of life (QoL) will be assessed by means of validated questionnaires.

### Secondary outcome

Quality of life (QoL) will be assessed by means of validated questionnaires.

## Study description

### Background summary

The routine therapeutic drug monitoring of CsA using predose **\*\*trough\*\*** concentration (C0) is accepted practice. Pharmacokinetic studies in renal transplant patients found that the 12-hour area under the concentration\*time curve (AUC[0\*12h]) is a very sensitive predictor of acute rejection incidence and graft survival at 1 year post-renal transplant [69] and that it is the best estimate of overall drug exposure, but it is not practical for routine clinical management.

Development of the Dry Blood Spot (DBS) sampling have made AUC[0-12h] monitoring more feasible. Patients can perform the fingerprick at home, no invasive procedure is necessary and monitoring at any desired sampling time can be undertaken conveniently

Objective: The number and severity of adverse drug reactions (renal function, nausea and tremor) of cyclosporine using AUC targeted Therapeutic Drug Monitoring as compared to C0 targeted TDM.

### Study objective

The number and severity of adverse drug reactions (renal function, nausea and tremor) of cyclosporine using AUC targeted Therapeutic Drug Monitoring as compared to C0 targeted TDM.

### Study design

Single-blind monocentre intervention study

## **Intervention**

CsA monitoring and dose adjustments will be based on trough levels (arm 1) or abbreviated AUC[0-12] (arm 2).

## **Study burden and risks**

One intravenous sample of blood in the clinic will be changed to 3 fingerprick samples collected by the patient. The patient will answer an 81 item QoL questionnaire 3 times. The risks associated with the investigational procedure is negligible and the burden minimal.

## **Contacts**

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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 18-65 inclusive
- \* AML, MDS, ALL, MM, CML, CLL, NHL, HL, or a myeloproliferative disease (MPD)
- \* Planned allogeneic stem cell transplantation
- \* Related or unrelated donor with a 7/8 or 8/8 HLA match (HLA A, B, C, DRB1) or 9/10 or 10/10 MUD match
- \* WHO performance status 0-2

## Exclusion criteria

- \* Renal dysfunction (serum creatinine > 150 umol/L or clearance < 50 ml/min)
- \* Patients with active, uncontrolled infection
- \* Cord Blood transplantation
- \* Patients with progressive disease in case of MM, CLL, NHL, HL
- \* Patients with > 5% marrow blasts in case of AML, ALL, CML
- \* Patients with EMD in case of AML, ALL, CML

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2014
Enrollment:	60
Type:	Actual

## Ethics review

Approved WMO

Date: 13-01-2014

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 14-11-2014

Application type: Amendment

Review commission: METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 27177

Source: NTR

Title:

### In other registers

Register	ID
CCMO	NL42166.029.13
OMON	NL-OMON27177