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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Leukaemias
Study type	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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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: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42166.029.13
OMON	NL-OMON27177