TRough vs AUC Monitoring of cyclosporine:
A randomized comparison of adverse drug reactions in allogeneic stem cell recipients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27177

Source
NTR

Brief title
TRAM study

Health condition

allogeneic stem cell transplantation
cyclosporine
TDM
Adverse drug reactions

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

- Grade acute kidney injury

- Grade nausea

- Grade in tremor

Secondary outcome

Adverse drug reactions

- Headache

- Hypertension

Clinical chemical parameters:

- Glucose

- Potassium

- Magnesium

- Total cholesterol

- High-density lipoproteins

- Liver function

Other parameters:

- Grade GVHD

- Minimal residual disease on day 28; 56; 84; 112; 140 ; 168

- Engraftment

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

Study description

Background summary

In this study the Therapeutic Drug Monitoring of cyclosporine with dried blood spot is investigated in allo SCT recipients. 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 design: Single-blind monocentre intervention study
Study population: Patients planned to undergo an allo SCT for malignant hematological disorders and with a related or unrelated 8/8 HLA matched donor are eligible for randomization.

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.

Intervention

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

Contacts

Public

[default]
The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

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

- Written Informed Consent

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:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2014
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-02-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39871
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4742
NTR-old	NTR4996
CCMO	NL42166.029.13
OMON	NL-OMON39871

Study results