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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27177

Bron
NTR

Verkorte titel
TRAM study

Aandoening

allogeneic stem cell transplantation
cyclosporine
TDM
Adverse drug reactions

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Grade acute kidney injury
- Grade nausea
- Grade in tremor

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

[default]
The Netherlands

Wetenschappelijk

[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2014
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-02-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39871
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten