Determination of cyclosporine levels in central venous blood samples versus peripheral blood samples: a clinical validation study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON50893

Source
ToetsingOnline

Brief title
VCSA study

Condition

- Other condition

Synonym
Cyclosporine blood level, cyclosporine medication level

Health condition

Allogene stamceltransplantatie

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blood collection, Central venous catheter, Cyclosporine, Venipuncture

Outcome measures

Primary outcome

Difference between the CsA levels in blood collected from the CVC versus blood

collected by means of a venipuncture.

Secondary outcome

n.a.

Study description

Background summary

An allogeneic stem cell transplantion (alloSCT) is used for various haematological diseases. It involves the intravenous infusion of blood-forming stem cells from a donor. After an alloSCT, alloreactivity can occur in two directions. Host-versus-graft alloreactivity resulting in rejection of the graft and graft-versus-host alloreactivity which may result in graft-versus-host-disease (GVHD). The transplantation is successful if the graft is not rejected by the patient and the blood cell formation has been taken over completely by the donor stem cells. In addition, it is important that GVHD, caused by donor T-cells attacking the healthy cells and tissues of the patient, does not occur or only to a limited extent. For this reason, during and after the transplantation immunosuppressive medication is needed to suppress the alloreactive T cells. One of the most important immunosuppressants is cyclosporine A (CsA).

The large pharmacokinetic variability of immunosuppressants between patients can lead to under- and overexposure with serious consequences. To ensure adequate exposure to immunosuppressants, drug doses are adjusted based on

measurements of whole blood concentration, also called therapeutic drug monitoring. During the first days to weeks after transplantation, patients are treated with CsA intravenously (iv), because patients may have symptoms of nausea, vomiting, and mucositis prohibiting the swallowing of tablets. During this period, CsA levels are measured three times a week in peripheral blood taken by means of a venipuncture even though all patients have a central venous catheter (CVC).

Patients experience the venipunctures as burdensome as punctures are often difficult due to the previous chemotherapy patients have received. In addition, as laborants are needed to perform the venipunctures, the procedure may lead to errors due to miscommunication between the nurses and the laboratory staff. Therefore, the aim of the current study is to investigate whether CsA levels measured in central venous blood samples collected by the nurses give reliable values. To determine if levels are indeed reliable, levels will be compared to the level of CsA measured in peripheral blood collected by means of a venipuncture at the same time.

Similar studies have already been performed. However, the opinions of researchers about the reliability of a central venous CsA level during simultaneous central administration are different. The interpretation of the available studies is complicated by the use of different types of CVCs and different methods to prevent so-called contamination of the collected blood sample. Conclusions cannot be translated directly into daily practice in the clinical haematology department of the EMC. Therefore, a practice-oriented study will be set up to test whether the results of the centrally collected CsA blood level are reliable when CsA is administered simultaneously using a silicone CVC.

Study objective

The aim of the study is to compare the CsA level in blood collected with a venipuncture with the CsA level in blood collected from the CVC during administration of CsA through the CVC. This to test the reliability of CsA levels in central venous blood samples. Furthermore, the effect of prolonged intravenous administration of CsA on the CsA levels in central venous blood samples will be examined

Study design

The study will have a quantitative research. This in order to gain numerical insight into the research problem of the CsA blood level and also to gain insight into the experiences of the nurses.

Study burden and risks

The patient's blood will be drawn from the CVC three times a week as long as the patient receives the cyclosporine intravenously. On average this will be 2 to 3 weeks adding up to 6 to 9 blood samples. Risk and strain is not expected as blood is already taken from the CVC, this will be an additional blood collection with 10ml blood.

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

* Eighteen years or older;
* Treated with an allogeneic stem cell transplant;
* CVC with at least 2 lumens;
* Treatment indication for intravenous cyclosporine;

* Understanding the Dutch language in words and writing;

Exclusion criteria

- Earlier treatment with intravenous cyclosporine through the CVC;
- CVC with less than two lumens

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-04-2021
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	30-03-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL75803.078.21