19004 Projectvoorstel Tania Khartabil en Henk Russcher

Titel/ Title	Application of hemocytometry biomarkers related to transfusion management during allogenic stem cell transplantation.
Onderzoeksteam/ Research team	Tania Khartabil (PhD-student) Henk Russcher (principle investigator) Peter te Boekhorst (member) Yolanda de Rijke (promotor)
Status	~~Project voorstel~~ // **Protocol in ontwikkeling** // ~~Definitief protocol~~
Samenvatting (Rationale)/ Abstract Onderzoeks-doelen/vragen Research goals/questions	The purpose of this study is to evaluate whether hemocytometry biomarkers could guide thrombocyte transfusion management during allogenic stem cell transplantation (ASCT). This is a pilot observational study and based on the results, a larger clinical study would have to take place to obtain conclusive evidence that transfusions could be managed in more efficient way by monitoring patients immature platelet fraction (IPF) together with platelet (PLT) values. The scope of these studies includes collecting and processing of residual whole blood samples from patients receiving stem cell transplantations. In addition, residual material from the platelet donor unit will also be collected for testing. All residual samples collected will be processed on the Sysmex XN-1000.
Design	The following parameters will be investigated: %IRF, #IRF, MCV, RDW, HGB, %IPF, #IPF, MPV, PLT-I/-O/-F, TPO (if possible to test in EDTA), %NEUT, #NEUT, %IG, #IG, CRP. The transfusion team will notify the laboratory for each PLT transfusion needed by the ASCT patients. For the duration of the study, the laboratory will know to run a full panel of parameters for these patients on the XN-1000 (RET/PLT-F) both pre and post transfusion in order to obtain the parameters needed. Samples are usually processed on the XN-1000, but for this study all possible PLT parameters will be tested including PLT-F. If a patient is new and not known to need HLA-typed PLT, but it is discovered during the study that they do in fact need HLA-typed platelets, both the non-HLA and HLA donor material will be obtained and this will be documented. ASCT patients needing PLT transfusions are transfused once a day (usually one bag but sometimes two bags at the same time). PLT counts are measured at 8 am in the morning, 1 hour after transfusion and at 8 am the following day. EDTA tubes will be collected pre-transfusion as well as during these two time points and processed on the Sysmex XN-1000 system. These results will be continually monitored until bone marrow (BM) recovery is evident. Official repopulation is determined by neutrophils> 1.0 and thrombocytes >100 x 10^3/µL. For example, patients with AML who do not fully repopulate may have a CRi or CRp as a response (complete remission with incomplete recovery / CR with incomplete platelet recovery). After allogeneic SCT we refer to engraftment if there are 2x measurements neutrophils >0.50 and thrombocytes >20 or >100 x 10^3/µL (depending on protocol). In addition to these three time points, all PLT parameters (%IPF, #IPF, MPV, PLT-I/-O/-F) in addition to some R&D platelet parameters (H-IPF%, PLTF-Y, PLTF-Z, PLTF-X, PLT-WX, and PLTF-WY) will be taken from the donor PLTs using any residual material left from the donor unit. Once transfusion is completed, the donor bag and tubing

	will be brought to the lab where the residual contents will be transferred into a tube and processed on the XN-1000. The main purpose of the study is to determine if platelets transfusions, particularly HLA-typed platelets, can be avoided based on the IPF biomarkers of patients prior to transfusion and their time to reach BM regeneration. Additionally, data will be obtained from the donor units as well to determine if there is a correlation between IPF and PLT values within the donor units and the time it takes the patient to get to BM recovery.
Publicatie mogelijkheden Leden/ Publication possibilities	
METC verklaring/ METC statement	Available, not WMO-plichtig.
Overig/ additional	