Bijlage programma Consortium voorjaarsbijeenkomst 29-3-2019:
Twee onderzoekspresentaties.

19001 'Foetaal reticulocytenbeloop bij IUT's voor ernstige HZFP', Isabelle Ree

Titel/ Title	Foetaal reticulocytenbeloop bij intrauteriene transfusies voor ernstige hemolytische ziekte van de foetus en pasgeborene
Onderzoeksteam/ Research team	**Isabelle M.C Ree, Carolien Zwiers, Marleen W.M. Janssen, Shannon K.S. Kroes, Dick Oepkes, Masja de Haas en Enrico Lopriore.**
Status	Project voorstel // Protocol in ontwikkeling // **Definitief protocol** // **Verwerking data/analyses en voorbereiding manuscript.**
Samenvatting (Rationale)/ Abstract	Het reticulocytengehalte bij de geboorte in kinderen die behandeld zijn met intra-uteriene transfusies (IUT's) vanwege ernstige hemolytische ziekte van de foetus en pasgeborene (HZFP), is lager ten opzichte van kinderen met HZFP die niet behandeld zijn met IUT's en deze behandelde kinderen hebben ook na de geboorte meer transfusies nodig [eigen data]. In deze studie wordt in een grote populatie van HZFP dit effect van IUT's nader bestudeerd door het foetale reticulocytenbeloop per IUT uit te zetten en te corrigeren voor mogelijke confounders.
Onderzoeks-doelen/vragen Research goals/questions	De primaire uitkomstmaat is de verandering (%) in foetaal reticulocytengehalte per IUT. Secundaire uitkomstmaten zijn veranderingen in het gehalte van foetale leukocyten en trombocyten per IUT en het aantal neonaten dat wisseltransfusie dan wel erytrocyten transfusies nodig heeft na geboorte per aantal IUT's.
Design	Observationeel cohortonderzoek.
Publicatie mogelijkheden Leden/ Publication possibilities	
METC verklaring/ METC statement	Niet WMO-plichtig onderzoek, "waiver of consent".
Overig/ additional	

19002 de PARAChUTe-studie, Rik Tonino, TRIP

Titel/ Title	Close Patient Monitoring in Chronically Transfused Low-Risk Myelodysplastic Syndrome Patients Receiving Young or Old Red Blood Cell Transfusions, a Single Blind Randomized Controlled trial.
Onderzoeksteam/ Research team	Principal investigator: M.S. Schipperus Coordinating investigator: R.P.B. Tonino
Status	Protocol in ontwikkeling
Samenvatting (Rationale)/ Abstract	The age of red blood cell (RBC) concentrates and the through storage caused damage, often referred to as the storage lesion, is a controversial topic. In a subgroup of patients that need RBC transfusion regularly, due to bone marrow failure, such as in myelodysplastic syndromes, striking differences in RBC concentrate quality might very well make a large difference. Therefore, regularly transfusing them with poorer quality RBCs could cause harm in a cumulative way, perhaps releasing a larger amount of NTBI and provoking different cytokine profiles or simply by a shorter survival time of transfused erythrocytes.
Onderzoeks-doelen/vragen Research goals/questions	**Primary objective** Compare the Hb increment after transfusion of young (<7d) RBC concentrates to that of standard and old (>28d) RBC concentrates in chronically transfused low-risk MDS patients. **Secondary objectives** Compare the NTBI-levels and transferrin saturation after transfusion of young (<7d) RBC concentrates to that of standard and old (>28d) RBC concentrates; Compare the cytokine profile after transfusion of young (<7d), standard and old (>28d) RBC concentrates; Correlate Quality of Life to Hb-level and RBC transfusions; Compare the difference in heart rate the night before and the night after transfusion with young (<7d), standard and old (>28d) RBC concentrates. To detect transfusion reactions in an early stage using the VitalPatch™;To determine the chronically transfused low risk-MDS patient's RBC transfusion need by monitoring the heart rate using the VitalPatch™.
Design	This is a phase 3B, double blind multicenter randomized controlled trial in which 33 low risk myelodysplastic syndrome (MDS) (IPSS 0-1) patients will be enrolled. Patients will be randomized in three groups: young(<7d), regular (no selection) or old (>28d) RBC's. In order to ascertain differences in the transfusion quality of young versus standard or old RBC units, in chronically transfused MDS patients Hb increment after transfusion is determined as well as the increment of serum iron (transferrin bound and non-transferrin bound). Also, adverse events will be registered and QoL questionnaires will be filled out by the patients. Donor properties like age and gender and patient properties like chronic iron overload status and management, signs of inflammation peri-transfusion and the presence of comorbidities are collated. In addition to blood tests and questionnaires, patients will be asked to wear a VitalPatch™ continuously during the study. The VitalPatch™ measures, amongst others, heart rate, respiratory rate and skin temperature. We aim to correlate vital signs to Hb, transfusion reactions and QoL. Furthermore, we expect to be able to detect transfusion reactions in an early stage, even when patients are at home due to the patch.
Publication possibilities	Peer reviewed journals
METC statement	Volgt
additional	-