

# Minutes NTTSG 30. April 2015-04-30

**Meeting number 32**

**Place: Hilton Copenhagen, Denmark**

**Participants:**

Oslo: Arnt Fiane; Odd Geiran, Inga Leuckfeld, Øystein Bjørtuft

Helsinki: Karl Lemström

Lund: Ingrid Skog; Johan Nilsson, Göran Rådegran; Hillevi Larsson

Göteborg: Göran Dellgren; Gerdt Riise; Ulla Nyström; Kristjan Karason

Copenhagen: Martin Iversen (chairman); Hans Henrik Schultz

Aarhus: Elisabeth Bendstrup

Scandiatransplant: Ilse Weinreich;

Minutes: Hans Henrik Schultz

**Welcome and presentation.**

Martin Iversen welcomed everybody to the meeting, and announced his retirement after 8 years as chairman for the NTTSG. Martin Iversen gave a brief overview of the structure of Scandiatransplant.

Ilse Weinreich gave an introduction to the change of Solid organ groups. Lot of work in Scandiatransplant office at the moment; The user face and registration of patients will be changed, and it is currently under in testing of “real users”, so the interface of registration of donors, recipients will be changed shortly. After that, she gave an overview of the registrations the last two years, with various but usually low rate of success. The question is if we want to continue in this way and if we find the current registrations acceptable? Do the parameters in the dataset have to be revised? All agreed to continue the register, and we probably could do better after the introduction of a new user face. It was agreed that for the next NTTSG meeting we should look at the parameters to be registered. Some core values that could be registered retrospectively, and a set of mandatory values to be registered prospectively.

Hans Henrik Schultz presented the analysis of the outcomes of the urgent call system. The introduction of the urgent call system has not impacted the mortality on waiting list; the waiting time on the waiting list, and the survival after lung transplantation is the same in the era before and after Urgent Call even comparing with the urgent call cohort. Hans Henrik Schultz will send out synopsis for ethical approval applications as well as CRF forms within few weeks.

Ulla Nyström showed the cumulated number of thoracic organ transplanted patients.

Martin Iversen: There was a general discussion on the urgent waiting list. Do we need to change the rules? Can you use one slot for next year, or do we need a payback system equivalent to the liver allocation? Or do we increase the fixed number to 4? Should an urgent

call still count if the patient dies while waiting? The system may have to be changed in the future, but for now it is the best system available and it was concluded to continue the way it is now.

## **Lunch**

Next Meeting was planned: October 19th 10-16:30 Hilton Copenhagen. New chairman have to be decided at that meeting. Candidates are urged to send their candidacy 1 month in advance.

Johan Nilsson: showed the presentation "*Prediction of primary graft dysfunction after heart transplantation*" recently presented in ISHLT2015 in Nice, France.

Primary graft dysfunction (death within 30 day mortality or re-transplantation) Proposed the registration of risk factors for primary grade dysfunction prospectively in all patients listed for heart transplantation in Scandiatransplant.

Göran Dellgren: "Three decades of Heart transplantation in Scandinavia: A long term follow up. Proposed a LVAD Scandiatransplant registry as bridge to transplantation. Both LVAD and ECMO as a bridge to transplantation. All centres present agreed to participate in the study.

Göran Dellgren: ScanCLAD study. Astellas has agreed to support the study. 121 recipients in each arm comparing Bi-daily Ciclosporin to once-daily Tacrolimus. Primary objectives are CLAD at 3 years and GFR at 3 months. Astellas will provide 7.800.000 SEK, which is enough to cover all staff salaries, but will not be enough to cover extra biopsies and CT scans, Cr-EDTA GFR's and GCP monitors. All centres need to think of ideas for sub-studies, ask our administration for allowance for going ahead, and identify research staff, and locally see to the application for Ethics, data and Drug agency application. Deadline for finished protocol and ethical approval is Q4 2015. All centres committed to participate in the study and within 2 weeks send mail with to names (a senior and a "deputy" preferably a pulmonologist and a thoracic surgeon).

A data safety and managing board and a clinical event comitee to report SAE has to be established. A working committee meeting has to established.

## **Tentative milestones:**

Working committee meeting end of May, and end of August.

Final protocol to be finished for submission by September 1<sup>st</sup> 2015.

Ethical application October 1<sup>st</sup> 2015

Drug agency application and data inspection agency application October 1<sup>st</sup>. 2015

Building electronic Case Report Form (eCRF)

Study start preferably January 1<sup>st</sup> 2016

## **Protocols for substudies will be written and finished in each centre:**

Immologist in Lund?

T cell function Oslo?

QOL Göteborg?

Oral glucose test and PGD in Copenhagen.

## **Suggestion for centrewise audit internally in NTTSG?**

