Nordic Pancreas and Islet Transplant group

Date: 11th October 2023

Location: Clarion Arlanda Sweden (Meeting Room – Leonardo Da Vinci) or Zoom Link

Participants:

Torbjörn Lundgren surgeon Stockholm, Torsten Eich immunology Uppsala and Stockholm, Olle Korsgren Islet lab Uppsala, Anna Ørskov Scandiatransplant, Kristine Fasting surgeon Oslo, Monica Olofsson transplant coordinator Oslo, Lydia Junebjörk research nurse Uppsala, Amanda Skog research nurse Uppsala, Marko Lempinen surgeon Helsinki, Bengt Gustavsson surgeon Gothenburg, Bengt von Zur-Mühlen nephrologist Uppsala, Hanne Scholz Isletlab Oslo. On Zoom: Trond Jenssen nephrologist /diabetology Oslo

1. Torbjörn Lundgren welcomed participants and was elected chairperson for the meeting. Bengt von Zur-Mühlen was elected secretary.
2. Introduction of participants
3. Agenda was approved, no additions.
4. Minutes from last on-line meeting 29th March 2023. An addition to the guidelines for cell therapies and ATMPs was desired and this is now implemented. Regarding the registries, there is a meeting on Nov 1st 2023. The minutes were approved.
5. Short report from centers regarding activities.
    a. Oslo: 2 SPK, 1 PA no graft loss, 8 on waiting list 50 % SPK. No islets yet this year but 2 on the waiting list
    b. Gothenburg: 2 SPK and 2 multi of which one died of GVH. No completed islets but with those on the way in 8 on the waiting list. During the year, Bengt Gustavsson hands over responsibility to John Söfteland
    c. Uppsala: 5 pancreas whereof 1 PA. 1 islet in march, 3 on the waiting list, 2 more listed soon and 7-8 in pipe-line.
    d. Copenhagen: 2 SPK, the second developed a thrombosis and graft loss
    e. Helsinki: 21 SPK with no graft loss but some complications, 1 PA. No islets but the project is ongoing with 1 SIK expected to be listed soon. The oldest pancreas recipient was 60 years.

f. Stockholm: Recent years 5-10 pancreas/year, 5 SPK and 1 PA so far this year. This year islets in March and May, one uncomplicated and the second relisted for second dose.

g. Malmö: 2 pancreas (No representant from Malmö at the meeting)

h. Scandiatransplant: A new service is ongoing and will give the centers able to share CT images in YASWA or a parallel system if needed.

6. Allocation of whole pancreas: It is decided that pancreas AND kidney should be offered if possible. Payback of kidney. However single pancreas is disproportionately often offered. To some degree (but not all!) this could be explained by complex priority rules regarding kidneys.

   Pancreases sent to the islet labs: Compared to before, there are fewer patients on the waiting list, which may explain why donation teams refrain from removing the pancreas. Stop during Covid etc could also be reasons. Upper donor limit 65 years for clinical islet transplantation. However, there are now about 15 patients waiting for islets and a new focus is important regarding offering pancreases to the islet labs. The discussion resulted in better attempts to identify pancreas donors in the first place rather than raising the age limit for donors. In Sweden this year have been 70 organ donors younger than 50 - 16 pancreas tx, 3 islet tx but around 20 where not offered to lab. Monica will bring this up at the Nordic coordinators meeting in November.

   The lab now receives cost coverage from the universities for a maximum of 20 research isolations per year. Discussion about joint waiting list for islets and pancreas where there are international centers with scoring systems. A short discussion about transplanting islets from patients with impaired glucose tolerance or T2DM. Studies show that poorer results can be expected.

7. News from The Islet Labs, Oslo and Uppsala: Leiden in Holland has developed a machine that can separate the endocrine from the exocrine – PRISM – Pancreatic Islet Separation Method. https://www.health-holland.com/project/2017/improved-pancreatic-islet-isolations-using-a-highly-automated-technique The current machine COBE 2991 used by all centers in Europe goes out of service next year (in Europe not US). Last week the first isolation performed using PRISM was transplanted to a patient in Leiden. A company (https://www.biorepdiabetes.com/biorep-technologies-inc-and-leiden-university-medical-center-lumc-sign-letter-of-intent-to-commercialize-prism-system/?v=1d20b5ff1ee9) has been given the task of manufacturing the machine commercially. It is expected to be expensive and not yet CE-marked. An alternative is cooperation with US, where the old machine is still in use. Our labs hope to still be able to use Cobes and import what is needed through the US

   Pancreases for research. **The Helmsley Charitable trust- type 1 diabetic donors** etc. Have there been any more? Have we missed any opportunities? During the year,

there have been 6 organ donors with type 1 diabetes, but no pancreas was offered to islet-lab. In some cases there has been a no for research, but at least two seem to have been missed. Monica will bring this up at the Nordic coordinators meeting in November.

Finland needs to complete the research plan and apply for ethical approval. Finland also has other legislation regarding organs for research. Marko L talks to Kaisa Ahopelto. By law, Denmark cannot use organs for research, at least abroad.

8. Ongoing studies:

VX-880 is an investigational allogenic stemcell-derived fully differentiated insulin-producing islet cell therapy manufactured. 90-days data for six US-patients have now been presented at the EASD meeting in Hamburg. It seems to take some time before the cells mature. The cells are transplanted as aggregated islets. Part C of the study will also start outside of the US (Europe), and Oslo as part of the NNCIT is ready. However, its difficult to find patients who meet all inclusion criteria (with for example 2 severe hypoglycemic avent with the last year) and specific blood group.

NNCIT02 is considered for 18 patients, low molecular dextran sulphate. 5 centers in Sweden, Norway and The Netherlands. 4 patients transplanted in Stockholm. Urgent need to transplant more. Patients on waiting list in Gothenburg among other centers.

9. Registries "MedSciNet" – Scandiatransplant - ESOT. Pancreas and Islets. What do we want – what are we missing? Technical meeting planned later this month. New islet data is entered in YASWA, but old data in NIR (MedsciNet) has not been migrated. Registration in YASWA has worked well in Uppsala. Discussion on common waiting list at Scandiatransplant.

   Finland enters pancreas data annually and this work continues. Unclear if evaluation of pancreas has started.

   Regardless of where a common waiting list is located, the clinic needs to prioritize the patients on the waiting list. The meeting agreed that Torbjörn Lundgren coordinates the clinical priority in Sweden together with representative from donor hospital so that the lab can set up adequate sera etc. for cross match.

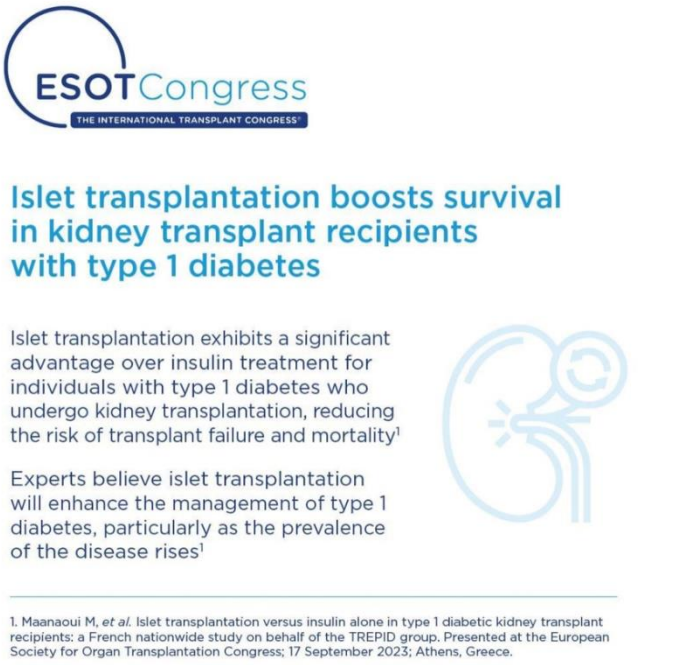
10. Working groups. In terms of experience, it has been difficult to get things going in the working groups between the regular meetings.

    Thorbjörn Lundgren has called *The registry working group* with a meeting date in November.

Auto program: Discussion on collaboration with gastrosurgeons a joint Nordic registry. Some data such as pain/QoL differs from our data. Hanne to discuss with Anne W and Morten H in Oslo to understand what we can do together.

Recruitment and endpoints: Important to start a working group to improve the numbers on our waiting lists. One working group should be able to define inclusion criteria and endpoints. Trond Jenssen coordinates the group and Torbjörn Lundgren, Hanne Scholz and Bengt von Zur-Mühlen joins. Trond will arrange a meeting in the group prior to end of January (where the EPITA Igls meeting take place which also plan to discuss this matter for Europe´s centers).

11. Any other business. Hanne Scholz referred to an abstract at ESOT where a French group (Lille) showed that islet transplant improve kidney graft survival and recipient mortality compare to intensive insulin therapy.



12. Next meeting Tuesday 16th April 2024, digital 13:00-16:00 CET. We need to invite the diabetologists to this meeting to discuss the perceived danger of immunosuppression in relation to such a large number of patients with diabetes having seriously high HbA1c despite the range of sensors and treatments. Vertex study etc could also be presented to them.

Secretary for the meeting	Chairman for the meeting
Bengt von Zur-Mühlen	Torbjörn Lundgren