

HUMAN ISLET FOR TRANSPLANT AND RESEARCH. R. NANO

State-of-art and future development/perspectives of the research area at international level (max 2000 characters):

Human islet transplantation is a well established approach to beta cell replacement in the treatment of insulin-deficient diabetes, applied in allogeneic and autologous patients. Even if it is recognized as successful clinical option and for this reason submitted to the rules of tissue transplantation (specific donor selection, GMP-like factory of production, periodic certification audit by the authority), it is not refunded everywhere as a specific clinical treatment, with great problem of sustainability of a transplant program.

On the other hand, the success rate of islet isolation, intended as number of preparations suitable for transplant/total number of performed isolations, is approximately 25% for not sufficient purification or low islet quantity, with evident increase in the overall cost of the procedure.

These reason and more recently, the increase of interest in insulin secreting stem cells have provide to maintain an active program of islet transplantation in centers with already consolidated experience in this field.

Actual lines of research (as is) of the Diabetes Research Institute (max 2000 characters):

We maintain an active program of allogeneic and autologous islets transplantation in OSR and a collaboration with Pancreatic Surgery Units of I.C. Humanitas and AOUI Verona for the islets preparation for autologous transplantation.

As center of European Consortium for Islet Transplant and with the authorization of OSR Ethical Committee, we have distributed human islets for research for studies already approved by local IRB until last November 23th, when Italian Health Ministry has communicated the impossibility to allocate tissue not suitable for transplant to research, according with current legislation. After this communication only tissue derived from living donors that have released an informed consent use for research could be used.

Strengths of the research area (as is) of the Diabetes Research Institute (max 2000 characters):

- 1) A facility suitable for islet processing with a quality assurance system already certified by the authority in an hospital with a Transplant Unit and Pancreatic Surgery Unit that sustain this activity.
- 2) In case of insufficient number of islets for transplantation, the possibility of an alternative use for research both inside OSR and in important European centers.

Weaknesses of the research area (as is) of the Diabetes Research Institute (max 2000 characters):

- 1)Recent communication about the impossibility to use for research all the tissue harvested from deceased donors and not suitable for transplant. This problem is currently much discussed with the other tissue institutesbut the timing for a decisive action are uncertain .
- 2) the availability of tissue from living donor is very low compared to that of deceased donors and actually does not represent a valid alternative to sustain research activity.

Short-medium term OSR/UniSR goals (0-18 months): milestones and deliverables (max 1000 characters):

- 1)To promote, together with the other tissue institutes, a revision of the current regulations that foresee the possibility of using for research purposes of tissues not suitable for transplantation, otherwise destined to be destroyed.
- 2)Involve the Pancreatic Surgery Unit to increase the number of organs pancreatectomized patients from that would otherwise be destroyed to improve our ability of isolation from small organ pieces.

Medium term OSR/UniSR goals (18-36 months): milestones and deliverables (max 1000 characters):

To promote, together with the other tissue institutes, a revision of the current regulations that foresee the possibility of using for research purposes of tissues not suitable for transplantation, otherwise destined to be destroyed.

Long term OSR/UniSR goals (36-60 months): milestones and deliverables (max 1000 characters):

NA

Investments of the Diabetes Research Institute (e.g. personnel, space, technology) to achieve the short-medium-long term goals (max 2000 characters):

NA