

The aim of this research is to establish the safety and practicality of using a machine which pumps cold oxygen-enriched preservation fluid in preserving pancreases for transplantation and to explore the potential benefits of using such technology.

Background

Pancreas transplantation can be an effective treatment in diabetic patients with the most severe complications. It can improve quality-of-life and survival by achieving insulin independence. Its limited use is due to the risk of complications, which can be life-threatening.

Tissues sustain damage because of lack of oxygen and nutrients while in between donor and recipient. When organs are retrieved, they need to be preserved in a way which minimises this damage. At present the current standard for preserving the donated pancreas by surrounding it with preservation fluid and keeping it cool by packing in an ice box. This method is safe as the cold temperature slows down metabolism, therefore decreasing the oxygen and energy needs of the tissues. This decreases the anticipated damage.

We propose using a machine to pump cold oxygen-enriched preservation fluid through the donated pancreas. This preservation technique has showed great promise in liver and kidney transplantation.

In the liver it was shown to

- Decrease damage to the tubes that carry bile out of the liver.
- Have protective effects against the damage linked to restoring blood supply to the liver in the recipient.
- Decrease rate of early liver impairment after transplantation.

In the kidney, it led to

- Better kidney function 12 months after transplantation
- Decreased possibility of the acute rejection, which is when the body recognises a transplanted kidney as foreign and activates the immune system to reject it.
- Decreased possibility of the transplanted kidney failing

Methods

The experiment will include 20 patients who will receive a pancreas and a kidney simultaneously from a deceased donor. The pancreas will be preserved using the standard method until it arrives to the recipient hospital, then it will be put on the machine before transplantation.

The effects of using this machine will be assessed by comparing measurable changes in the health of included patients to 40 similar patients who previously had the same kind of transplant in the same hospital.

The following effects will be studied:

- The effect on the frequency of inflammation of pancreas in the 30 days after transplantation.

- The frequency of further procedures or surgeries required after transplantation.
- Survival in the first year.
- The effect on possibility of failure of either pancreas or kidney in the first year.
- Blood tests to measure pancreas and kidney function.
- Length of hospital and critical care stay
- The frequency of acute rejection of the pancreas or kidney.
- The effect on frequency of delay in kidney function

The pancreases which will be declined for transplantation will be preserved using the suggested machine for a longer time in the laboratory or the standard method for the same length of time. Photographs and regular samples of tissue will be studied to compare both methods.

PPI group was involved in design of the experiment. PPI representatives will take part in the trial steering committee, dissemination and presentation of updates and outcomes.

This research will be disseminated through a monthly newsletter, which will be propagated to interested patients and public through signing up for the electronic or paper form and through communication to patient groups, charities, specialist medical areas and social media. As well as peer-reviewed publication and communication to learned societies.

This research has the potential of

Increasing the number of patients who benefit from pancreas transplantation.

Improving the safety profile of this treatment.

Possibility of decreasing the number of discarded pancreases.