Extended pancreas donor program - the EXPAND study rationale and study protocol.

Simultaneous pancreas kidney transplantation (SPK), pancreas transplantation alone (PTA) or pancreas transplantation after kidney (PAK) are the only curative treatment options for patients with type 1 (juvenile) diabetes mellitus with or without impaired renal function. Unfortunately, transplant waiting lists for this indication are increasing because the current organ acceptability criteria are restrictive; morbidity and mortality significantly increase with time on the waitlist. Currently, only pancreas organs from donors younger than 50 years of age and with a body mass index (BMI) less than 30 are allocated for transplantation in the Eurotransplant (ET) area. To address this issue we designed a study to increase the available donor pool for these patients. This study is a prospective, multicenter (20 German centers), single blinded, non-randomized, two armed trial comparing outcome after SPK, PTA or PAK between organs.
with the currently allowed donor criteria versus selected organs from donors with extended criteria.
Extended donor criteria are defined as organs procured from donors with a BMI of 30 to 34 or a donor age between 50 and 60 years. Immunosuppression is generally standardized using induction therapy with Myfortic, tacrolimus and low dose steroids. In principle, all patients on the waitlist for primary SPK, PTA or PAK are eligible for the clinical trial when they consent to possibly receiving an extended donor criteria organ. Patients receiving an organ meeting the current standard criteria for pancreas allocation (control arm) are compared to those receiving extended criteria organ (study arm); patients are blinded for a follow-up period of one year. The combined primary endpoint is survival of the pancreas allograft and pancreas allograft function after three months, as an early relevant outcome parameter for pancreas transplantation. The EXPAND Study has been initiated to investigate the hypothesis that locally allocated extended criteria organs can be transplanted with similar results compared to the currently allowed standard ET organ allocation. If our study shows a favorable comparison to standard organ allocation criteria, the morbidity and mortality for patients waiting for transplantation could be reduced in the future. Trial registered at: NCT01384006.

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