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Comparative Pancreas Induction Study

Submission date 27/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/01/2006	**Overall study status** Completed	
Last Edited 26/08/2009	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Added 26/08/09: An open label, randomised, study to assess the efficacy and safety of Zenapax® (daclizumab) or a single high dose of Anti-Thymocyte Globulin (ATG-Fresenius®) for the prevention of acute rejection in patients receiving de novo simultaneous pancreas kidney transplantation treated with CellCept®, Neoral® and corticosteroids.

Acronym
COMPAS

Study objectives
Equal in efficacy to prevent (biopsy-confirmed) early graft rejection and steroid-resistant rejection episodes in the first 6 months after a first simultaneous pancreas kidney transplantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre randomised open label active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Renal transplant, Pancreas transplantation

Interventions
Randomisation for the type of induction therapy:
1. Zenapax® (5 gifts of 1 mg/kg, with a maximum of 100 mg per dose, diluted in 50 ml of sterile 0.9% sodium chloride solution). The first dose will be administered intravenously before reperfusion of the first allograft. Subsequent doses of Zenapax® will be given 2, 4, 6, and 8 weeks after transplantation.
2. ATG-Fresenius® (single high dose of 9 mg/kg, diluted in 500 ml of sterile 0.9% sodium chloride solution). The iv infusion starts immediately after the central line is in place and the dose will be

administered before reperfusion of the first allograft.
All patients will be given 500 mg Solu-Medrol as an iv infusion thirty minutes before operation.
All patients will receive mycophenolate mofetil (2 g/day), cyclosporin A (CsA) and prednisone.
Dosing of CsA (target trough levels) and prednisone will be according to current hospital practice, aiming at cyclosporine trough levels of 200-300 ng/ml in the first three months, and 100-200 ng/ml thereafter.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Anti-Thymocyte Globulin (ATG-Fresenius®), daclizumab (Zenapax®), mycophenolate mofetil (MMF) (CellCept®), cyclosporin (Neoral®), prednisone

Primary outcome measure
The prevention of biopsy proven early graft rejection and steroid-resistant rejection episodes in the first 6 months after simultaneous pancreas kidney transplantation.

Secondary outcome measures
1. Recurrence of autoimmune disease parameters
2. Time to first rejection, time after last prophylactic dose and number of steroid-resistant rejection episodes at 3 and 6 months after transplantation
3. Graft and patient survival
4. Immunophenotyping peripheral blood lymphocytes (CD3, CD4, CD8 and CD25 respectively)
5. Adverse events and opportunistic infections
6. After the first year, patient and graft survival and the occurrence of graft dysfunction will be monitored and documented according to local practice

Overall study start date
01/10/1999

Completion date
01/06/2005

Eligibility

Key inclusion criteria
1. Type 1 diabetics (C-peptide negative) with (pre)terminal or end-stage renal failure scheduled to receive a simultaneous pancreas kidney cadaveric transplantation, with either bladder or enteric drainage
2. Patients scheduled to receive mycophenolate mofetil (CellCept®), cyclosporin (Neoral®) and corticosteriods as basis immunusuppression
3. Male and female patients >18 years old
4. Patients capable of understanding the purpose and risks of the study and from whom informed consent has been obtained

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Pancreas after kidney transplant (PAK), pancreas transplant alone (PTA), segmental pancreatic transplant
2. Duct occlusion technique
3. Induction therapy with OKT3 planned
4. Pregnant or nursing women and women unwilling to use adequate contraception during, and three months following the conclusion of treatment with MMF
5. Patients scheduled to receive FK 506 (tacrolimus) or Azathioprine as basis immunusuppression
6. Patients with severe gastrointestinal disorders, that interfere with their ability to receive or absorb oral medication and patients with severe diarrhea
7. Patients with active peptic ulcer disease
8. Patients or their donors with serologic evidence of HIV, Hepatitis C Virus (HCV) or Hepatitis B Surface Antigen (HBsAg) in the past
9. Patients with malignancies (current or history within last 5 years) except non metastatic basal or squamous cell carcinoma of the skin that has been treated successfully
10. Patients with systemic infection requiring therapy at the time of entry to the study
11. Patients being treated with unlicenced, investigational drugs or other prohibited medication
12. Patients with any form of substance abuse or psychiatric disorder which in the opinion of the investigator might invalidate patients communication with the clinician
13. Patients with known hypersensitivity to daclizumab or to any of the components of this product

Date of first enrolment
01/10/1999

Date of final enrolment
01/06/2005

Locations

Countries of recruitment
Netherlands

Study participating centre

Leiden University Medical Center
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details
Albinusdreef 2
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Industry

Funder Name
Roche Nederland BV (Netherlands)

Funder Name
Fresenius Medical Care (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2007		Yes	No