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Dutch Evaluation in Liver Transplantation To Assess the efficacy of Neoral® (cyclosporin A) with C-2h monitoring versus Prograft® (tacrolimus) with trough monitoring in de novo liver transplant recipients

Submission date 27/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 27/01/2006	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 15/04/2019	**Condition category** Surgery	[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00149994

Protocol serial number
NTR489

Study information

Scientific Title
Dutch Evaluation in Liver Transplantation To Assess the efficacy of Neoral® (cyclosporin A) with C-2h monitoring versus Prograft® (tacrolimus) with trough monitoring in de novo liver transplant recipients

Acronym
DELTA

Study objectives
There is a difference in rate of biopsy-proven acute rejection between a Neoral® regimen with C2 monitoring versus a Tacrolimus regimen with C0 monitoring.

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Liver transplantation

Interventions
Cyclosporin A with C-2h monitoring versus tacrolimus with trough monitoring in de novo liver transplant recipients (randomised controlled open trial) with anti-CD25 and prednisolone in both arms.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cyclosporin A (Neoral®), tacrolimus (Prograft®), anti-CD25 (Simulect®), prednisolone

Primary outcome(s)

The incidence of biopsy-proven acute rejection (BPAR) during the first 3 months post-transplantation.

Key secondary outcome(s))
Efficacy, safety, tolerability of both regimens:
1. Incidence of BPAR at 6 months
2. Incidence of BPAR with moderate/severe histological grading at 3 and 6 months
3. Patient death at 3 and 6 months
4. Graft loss with re-transplantation at 3 and 6 months
Biological liver function tests, selected lab parameters such as serum creatinine and glucose, recurrence of hepatitis C at 6 months, blood pressure values, lipid profiles, infections, occurrence of malignancies, Post-Transplant Diabetes Mellitus (PTDM) (treated and untreated), adverse events and serious adverse events, pharmakokinetic endpoints related to C0 and C2h levels and their correlation to clinical 3 and 6 months outcome.

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Patients about to undergo a primary liver transplantation
2. 18-75 years of age
3. Expected to be capable of participating 6 months post-transplantation
4. Allograft biopsies will be possible
5. Expected to be able to receive Neoral® or Prograft® within 48 hours post-transplant
6. Able to maintain the same immunosuppressive schedule for 6 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Multi-organ transplant
2. Previous transplant
3. ABO incompatible transplant

4. Not eligible to receive at least 10 mg/kg as initial oral dosing of Neoral
5. Seropositive for HIV antibodies
6. Urine production less than 200 ml within 12 hours after reperfusion of the graft
7. Mycophenolate mofetil, azathioprine and/or rapamycin is prescribed post-transplantation
8. Severe coexisting disease or any unstable medical condition is present which could affect the study objectives
9. An unlicenced drug or therapy has been administered within one month prior to study entry or such therapy is to be instituted post-transplantation

Date of first enrolment
25/12/2002

Date of final enrolment
31/12/2006

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)

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharma B.V. (Netherlands)

Results and Publications

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?
Basic results				No	No