

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/04/2019	Condition category Surgery	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00149994

Secondary identifying numbers

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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 (Prograf®), anti-CD25 (Simulect®), prednisolone

Primary outcome measure

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

Secondary outcome measures

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, pharmacokinetic endpoints related to C0 and C2h levels and their correlation to clinical 3 and 6 months outcome.

Overall study start date

25/12/2002

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 Prograf® within 48 hours post-transplant
6. Able to maintain the same immunosuppressive schedule for 6 months

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

124

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 unlicensed 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)

Sponsor details

Department of Gastroenterology - Hepatology
P.O. Box 9600
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Netherlands
2300 RC

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Industry

Funder Name

Novartis Pharma B.V. (Netherlands)

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?
Basic results				No	No