

# 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

<b>Submission date</b> 27/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/04/2019	<b>Condition category</b> 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  
Leiden  
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?
<a href="#">Basic results</a>				No	No