

## Trial Description

### Title

**Validation of the expression of NFAT regulated genes in a low dose cyclosporin liver transplantation immunosuppression**

### Trial Acronym

**NFAT Trial**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**Goal of the study is the validation of the expression of NFAT regulated genes in a low dose cyclosporin liver transplantation immunosuppression**

### Brief Summary in Scientific Language

**With the introduction of calcineurin inhibitors (CNI) in the immune suppression after organ transplantation graft survival was significantly improved . A major side effect of CNIs (Cyclosporin, tacrolimus) is their nephrotoxicity and the risk of infectious complications . In addition, patients who have no sufficient suppression of the NFAT-regulated genes show sufficiently high rejection in spite of cyclosporine (CyA) Levels.**

**Patients should therefore receive an individual therapy after transplantation taking into account the side effects on the one hand, and the potential risk of organ rejection on the other hand . Moreover, it should be noted that there may be a great deal of Profit for the patients' sake when the NFAT Pathway is also sufficiently suppressed. Analog to this is the detection of the effects of insulin by the determination of the blood sugar value and not by measuring insulin levels. Giese et al. have already shown in 2004 that the efficacy of immunosuppression with CyA can be reliably determined in long-term stable patients after organ transplantation by quantitative determination of the suppression of NFAT-regulated genes.**

**Study Design. Out of the total 20, patients will be stratified according to the classification according to Bruns et al. (2) Each Arm will entail 5 patients with a preoperative labMELD score MELD; model for end stage liver disease) between 6-10 (Group I), 11-18 (group II), 19-24 (group III) and > 24 (group IV) .**

**On postoperative days 3 and 7, before and 2h after CyA administration the expression of NFAT-regulated genes can be determined by PCR.**

## Organizational Data

- DRKS-ID: **DRKS00009597**
- Date of Registration in DRKS: **2015/11/04**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S-535/2012 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

## Secondary IDs

## Health condition or Problem studied

- Free text: **Liver Failure, Immunosuppression, Cyclosporin**

## Interventions/Observational Groups

- Arm 1: **Patients with preoperative MELD (Model for End Stage Liver Disease) score of 6-10:**  
**On days 3 and 7 after liver transplantation immediately before and 2 h after cyclosporine A administration a determination of the expression of NFAT-regulated genes by PCR will be performed.**
- Arm 2: **Patients with preoperative MELD (Model for End Stage Liver Disease) score of 11-18:**  
**On days 3 and 7 after liver transplantation immediately before and 2 h after cyclosporine A administration a determination of the expression of NFAT-regulated genes by PCR will be performed.**
- Arm 3: **Patients with preoperative MELD (Model for End Stage Liver Disease) score of 19-24:**  
**On days 3 and 7 after liver transplantation immediately before and 2 h after cyclosporine A administration a determination of the expression of NFAT-regulated genes by PCR will be performed.**
- Arm 4: **Patients with preoperative MELD (Model for End Stage Liver Disease) score of >24:**  
**On days 3 and 7 after liver transplantation immediately before and 2 h after cyclosporine A administration a determination of the expression of NFAT-regulated genes by PCR will be performed.**

## Characteristics

- Study Type: **Non-interventional**



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- Study Type Non-Interventional: **Other**
- Allocation: **Other**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Other**
- Purpose: **Pharmacogenetics**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

### Primary Outcome

**Validation of expression of the NFAT regulated genes (using PCR Expression Analysis) under treatment with a low dose immunosuppression regimen CyA**

### Secondary Outcome

**Correlation between CyA levels and suppression of the nfat genes in the time Frame of 2 hours after Administration of CyA.  
Correlation of nfat regulated genes in patients with stable immunosuppression Regimen on the one hand and patients' in the first week after LTx under low-dose CyA Immunosuppression.**

### Countries of recruitment

- DE **Germany**

### Locations of Recruitment

- Medical Center **Klinik für Allgemein-, Viszeral- und Transplantationschirurgie, Heidelberg**

### Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/11/09**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

### Additional Inclusion Criteria

- **First Transplantation**
- **Immunosuppression with low-dose CyA+Corticosteroid+MMF (Mycophenolatmofetil)**
- **Operation und postoperative treatment in the university clinic of surgery of heidelberg**
- **Patients treated with cyclosporine**

### Exclusion criteria

- **No IC**
- **Re-Transplantation**
- **acute Infection (CMV pp65 positive, Pneumonia, UTI, wound infection, reactivated hepatitis B/C)**
- **patients not able to receive oral CyA**

### Addresses

#### ■ Primary Sponsor

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#### ■ Contact for Scientific Queries

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### Sources of Monetary or Material Support

#### ■ **Private sponsorship (foundations, study societies, etc.)**

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URL: **<http://stiftung-chirurgie.de/kontakt.html>**

### Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): [---]\*

### Trial Publications, Results and other documents

\* This entry means the parameter is not applicable or has not been set.

\*\*\* This entry means that data is not displayed due to insufficient data privacy clearing.