Trial Description

Title

Prospective Institutional review trial to test de novo sirolimus monotherapy following antithmocyte globin induction in kidney transplant recipients

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Kidney transplant recipients with immunological low-risk to a acute transplantat rejection receive a minimize immunsuppression. The patients undergo a immunsuppression with a polyclonal antibody (Thymoglobulin®, antibody against many defence cells in blood) following de novo sirolimus (Rapamune®) monotherapy.This immunosuppressive therapy should reduce the risk of chronic allograft nephropathy. In all, it can be expected, that the steroid- and CNI-free protocol will be the risk of cardiovascular events and the related mortality as well as the risk of opportunistic infection beneficially influenced.
The control group is a historic patient population. These patients received standard medication treatments for kidney transplant recipients: cyclosporin, mycophenolatmofetil and steroids.
Planned recruitment: 1.1. 2005 till 31.12.2006. Planned closure of follow-up: 2010.

Brief Summary in Scientific Language

Nonsensitized recipients of human leukocyte antigen-nonidentical postmortal kidney grafst will enrol in a prospective trial to test de novo sirolimus monotherapy following antithymocyte globin induction. This steroid- and CNI-free protocol should reduce the risk of cardiovascular events, chronic allograft nephropathy and the risk of opportunistic infection.

Organizational Data

- DRKS-ID: **DRKS00000858**
- Date of Registration in DRKS: **2012/04/25**
- Date of Registration in Partner Registry or other Primary Registry: **2004/07/22**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **054/04 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Partner Registry-ID: **UKF000105 (Register klinischer Studien des Universitätsklinikums Freiburg)**

Health condition or Problem studied

- ICD10: **N18.8 - Other chronic renal failure**
- ICD10: **Z94.0 - Kidney transplant status**

Interventions/Observational Groups

- Arm 1: **15 well-selected immunologically low-risk patients receive a minimized immunsuppressive regime after kidney transplantation. The immunsupression starts with antithymocyte globin induction following de novo sirollmus monotherapy. This steroid- and CNI-free protocol should reduce the risk of cardiovascular events, chronic allograft nephropathy and the risk of opportunistic infection.**
- Arm 2: **Historic patient population treated with standard protocol: cyclosporine, mycophenolatmofetil, steroids**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Historical**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Transplant function (serum creatinine mg/dl and ceatinin-clearance) after 1, 3, 5 years

Secondary Outcome

- **patient- and transplant survival**
- **rate and degree of acute bioptic confirmed graft shedding(after Banff) and number of steroid-resistant sheddings**
- **intake of calcineurin-inhibitors**
- **steroid long-term medication**
- **incidence of Chronic Allograft Nephropathy (CAN)**
- **level of blodd pressure and antihypertensive medication**
- **lipid level and lipid reducing medication**
- **liver function**
- **rate and degree of oppertunistic infections**
- **incidence of an haematological adverse effect**
- **incidence of malignant disease**

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Chirurgie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2005/01/26**
- Target Sample Size: **15**
- 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 kidney transplantation
- ager 18 - 65 years
- Written informed consent
- Highly effective contraception

Exclusion criteria

- slave- or multi-transplantation
- combined transplantation
- age < 18 years
- incompatibility (allergy, intolerance, oversensitive) against study medication
- current malignant disease or last malignant disease< 5 years
- Serious intercurrent infections (uncontrolled or requiring treatment (incl. HIV)
- severe diarrhoea, vomiting or active gastric- or duodenal ulcer
- participation in another investigational sudy
- autoimmune disease as primary disease (collagen vascular diseases, colitis, HUS, SLE)
- primary disease focal-sclerotising glomerulonephritis
- disease, which need temporary or permanent treatment with cortisone (also inhalatory medicines)
-severe fat metabolic disturbance (cholesterine > 300 mg/dl, triglycerides > 400 mg/dl)
- Epstein-Barr-virus IgG negative
- chronic hepatitis B and hepatitis C infection
- thrombocytopenia < 50.000 tsd/µl
-coagulopathies (lack of or a defect in v. Willebrand factor, hemophilia, lack of protein S lack of protein C)

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- Study Closing (LPLV): **2005/11/29**

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.*