Trial Description

Title

**HARMONY-Follow-up-Study
(Triple Arm, Prospectively Randomized Multi Centre Study Phase IV to Evaluate Calcineurin Inhibitor Reduced, Steroid Free Immunosuppression After Renal Transplantation in Non-risk Patients)**

Trial Acronym

HARMONY-Follow-up

URL of the trial

[---]*

Brief Summary in Lay Language

**In the HARMONY-trial (EuCTR2007-006516-31-DE) different medicamentous immunosuppressive therapy strategies were investigated up to one year after transplantation. Especial-ly, it was looked for the best strategy to terminate the cortisone therapy.
Aim of this investigation now is, to reanalyze the outcome of the HARMONY-trial 3 and 5 years after transplantation during the routinely post-transplantational care and to gain additional blood and urine samples.
This will help to evaluate the long term achievements of the therapy strategies used in the HARMONY-trial.
In addition to this, using new experimental methods to analyze the new blood and urine samples together with the old ones from the HARMONY-trial should lead to new marker for early detection of graft rejections and infections as well as marker for regulation of immune suppression after kidney transplantation.**

Brief Summary in Scientific Language

**In the HARMONY-trial (EuCTR2007-006516-31-DE) the standard steroid therapy (Advagraf, CellCept, Decortin H + 2x Simulect day 0 + 4) were compared against steroidfree therapies (arm 2: Advagraf, CellCept, Decortin H until day 8, 2x Simulect day 0 +4; arm3: Advagraf, CellCept, Decortin H until day 8, 3x Thymoglubulin) up to one year after transplantation.
Especially, it was looked for the best strategy to terminate the cortisone therapy.
Aim of this investigation now is, to reanalyze the outcome of at least 500 patients the HARMONY-trial 3 and 5 years after transplantation during the routinely post-transplantational care and to gain additional blood and urine samples.
This will help to evaluate the long term achievements of the therapy strategies used in the HARMONY-trial.
In addition to this, using new experimental methods to analyze the new blood and urine samples together with the old ones from the HARMONY-trial should lead to new marker for early detection of graft rejections and infections as well as marker for regulation of immune suppression after kidney transplantation.**

Organizational Data

- DRKS-ID: **DRKS00005786**
- Date of Registration in DRKS: **2014/03/10**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EK 364092013 , Ethikkommission der Medizinischen Fakultät der Technischen Universität Dresden**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1154-2186**

Health condition or Problem studied

- ICD10: **Z94.0 - Kidney transplant status**
- ICD10: **[---]* - [---]***

Interventions/Observational Groups

- Arm 1: **In this study the intervention arms of the HARMONY study will be proved again, there will be no new intervention:**
  Intervention arm A:
  Standard: Advagraf, CellCept, Decortin H + 2xSimulect day 0 +4
- Arm 2: **In this study the intervention arms of the HARMONY study will be proved again, there will be no new intervention**
  Intervention Arm B - Steroid free:
  Advagraf, Cellcept, Decortin H until day 8, 2x Simulect day 0 + 8
- Arm 3: **In this study the intervention arms of the HARMONY study will be proved again, there will be no new intervention**
  Intervention Arm C -Steroid free:
  Advagraf, Cellcept, Decortin H until day 8 3x Thymoglobin

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Other**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Other**

- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

rate and severity of acute bioptical confirmed rejections (Banff)
time to the first bioptical verified rejection

Secondary Outcome

rate of patients with steroid-free immunosuppression
patient and graft survival rate
graft function (calculated by the Cock- croft-Gault and MDRD-IV formula respectively calculated creatinine clearance by the Nankivell formula respectively cystatin C measurement)
number of steroid-resistant rejections
blood pressure level and also amount and types of blood pressure medications
lipid levels and also amount and types of lipid-lowering medications
body weight, relative weight gain [kg], BMI
infection rate, infection type and infection severity
anaemia requiering erythropoetin treatment
PTLD incidence
tumor incidence
incidence of diabetes mellitus (ADA, venous fasting blood sugar >=7,0 mmol/L, pathological oGTT) and incidence of abnormal fasting blood sugar levels respectively of impaired glucose tolerance, incidence of a de novo insulin-requiriring or oral-antidiabetic-requiring treatment over >= 30 days
incidence of cataracts
incidence of avascular necrosis
incidence of osteoporosis (assessment of fracture rate and osteodensiometry)
wound healing disorders
incidence of chronic allograft nephropathy (CAN) with histology
incidence of CMV-disease (qPCR > 400 copies/µl)
incidence of BKV-disease (qPCR >10000 copies/µl)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/03/04**
- Target Sample Size: **500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **83 Years**

Additional Inclusion Criteria

Patients with kidney transplantation and taking part at the HARMONY-study patients with a signed informed consent form

Exclusion criteria

Patient who are not able to realize nature, relevance and consequences of the clinical trial and who are not able to comply, to cooperate and communicate adequately and to follow the instructions of the study or even to give their informed consent

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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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.*