Trial Description

Title

Conditioning of immunosuppressive effects in renal transplant patients

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In this study we investigate wether it is possible to condition an immunsuppresion in renal transplant patients. In rodents and healthy male test subjects a successfull conditioniing has already been shown. In this study we investigate wether a placebo intace in combination with a novel tasting drink can support the immunsuppression and prevent a decrease of the immunsuppression inbetween the drug intake in renal transplant patients, that take an immunosuppressive drug on a daily basis.
Therefore the patients drink the novel tasting drink as a conditioned stimulus simultaneously with the intake of their immunosuppressive drug. This paring takes place six times. After 7 days the drink is given with a placebo between the intake of the immunosuppressive drug in the morning and evening. It is expected, that the decrease of the suppressive effect, which arises after the intake of the immunosuppressive drug, is reduced.

Brief Summary in Scientific Language

In this study we investigate wether it is possible to condition an immunsuppresion in renal transplant patients. In rodents and healthy male test subjects a successfull conditioniing has already been shown. In this study we investigate wether a placebo intace in combination with a novel tasting drink can support the immunsuppression and prevent a decrease of the immunsuppression inbetween the drug intake in renal transplant patients, that take the immunosuppressive drug Cyclosporin A or Tacrolimus on a daily basis.
Therefore the patients drink the novel tasting drink as a conditioned stimulus simultaneously with the intake of their immunosuppressive drug. This paring takes place six times in the acquisition phase. After 7 days the drink is given with a placebo between the intake of the immunosuppressive drug in the morning and evening. It is expected, that the decrease of the suppressive effect, which arises after the intake of the immunosuppressive drug, is reduced.

Organizational Data

- DRKS-ID: **DRKS00007693**
- Date of Registration in DRKS: **2015/03/02**

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- 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.: **13-5572-BO , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **novel drink in addition to immunosuppressive drug intake in the morning in the evening on three days; drink and placebo capsules between the immunosuppressive drug intake in the morning and the evening on two days**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Analysis of the Interleukin-2- and the Interferon-Gamma-level and the proliferation of the t-cells 2, 6, and 10 hours after the immunosuppressive drug intake in the morning: On day 1 (Baseline), on which the conditioned stimulus has not been added yet, and on day 8, on which the conditioned stimulus is ingested together with placebo capsules 4 and 8 hours after the immunosuppressive drug intake in the morning.

Secondary Outcome

On day 1 and 8 we analyse the subpopulation of the peripheral blood mononuclear cells, the cortisol- and the catecholamine-level 2, 6 and 10 hours after the immunosuppressive drug intake in the morning. The blood pressure will also be measured.
Additionaly the probands give information about side effects and psychological parameters via standardized questionnaires about one week before and in the morning and evening on study-days 1-3, 8-10 and 15-17.
Following questionnaires were used:
SSAS, HADS, BIS/BAS, BMQ, PSQ, Adherence Scale Marburg, STAI-State, STAI-Trait, SWE, SFA-K, GASE-P, SES-17. Furthermore we asked for general frequency of side effects, estimation of probability of side effects and occurrence of specific side effects. We also asked for a estimation of the beverage concerning different dimensions.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Essen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/04/13**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

Additional Inclusion Criteria

stable renal transplant patients, at least 1 year after transplantation, stable function of the transplant, ability to understand the aims of the study and for informed consent, immunosuppressive therapy including a calcineurin inhibitor, lymphocytes depletion drug in the last 12 months

Exclusion criteria

minority, pregnancy, malignoma, active rejection, chronic infectious disease (HIV, hep A+B+C), BK-nephropathy, acute infectious disease at the time of inclusion

Addresses

- **Primary Sponsor**

  Universitätsklinikum Essen
  Mr. Prof. Dr. med. Oliver Witzke
  Hufelandstr. 55
  45122 Essen
  Germany

  Telephone: **02017233394**
  Fax: **[---]***
  E-mail: **oliver.witzke at uk-essen.de**
  URL: **http://www.uk-essen.de/nephrologie/**

- **Contact for Scientific Queries**

  Institut für Medizinische Psychologie
  Mr. Professor Dr. rer. biol. hum. Manfred Schedlowski
  Hufelandstr.55
  45147 Essen
  Germany

  Telephone: **02017234500**
  Fax: **02017235948**
  E-mail: **manfred.schedlowski at uk-essen.de**
  URL: **http://www.uk-essen.de/medizinische-psychologie/**

- **Contact for Public Queries**

  Institut für Medizinische Psychologie
  Ms. M.Sc. Anna Lena Kahl
  Hufelandstr. 55
  45147 Essen
  Germany

  Telephone: **02017233975**
  Fax: **02017235948**

Contact for Public Queries

Institut für Medizinische Psychologie
Ms. M.Sc. Anna Lena Kahl
Hufelandstr. 55
45147 Essen
Germany

Telephone: **02017233975**
Fax: **02017235948**
E-mail: **annalena.kahl at uk-essen.de**
URL: **http://www.uniklinikum-essen.de/medizinische-psychologie/**

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Deutsche Forschungsgemeinschaft
Kennedyallee 40
53175 Bonn
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.dfg.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2017/03/27**

Trial Publications, Results and other documents

- Paper **Learned immunosuppressive placebo responses in renal transplant patients**

** 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.*