

# Rationale and design of the TRANSNephro study examining transition of post-kidney transplant adolescents

<b>Submission date</b> 16/04/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 25/04/2014	<b>Overall study status</b> Completed	
<b>Last Edited</b> 04/04/2025	<b>Condition category</b> Urological and Genital Diseases	

## Plain English summary of protocol

### Background and study aims

The transition from pediatric nephrology to adult internist nephrology is not yet being carried out in accordance with uniform structuring. Consequently, there are increased risks of deterioration or loss of transplanted kidneys. The aim of this study is to enable the introduction of a sustainable structured transition of adolescent nephrology patients from pediatric to adult care to improve transplant survival.

### Who can participate?

All German pediatric kidney recipients aged 16-21 who will be transferred into adult care from 2014-2016

### What does the study involve?

In phase I, the patient transition situation in German nephrology departments is evaluated, including an evaluation of the present situation in the view of physicians, nurses and psycho-social support staff. In phase II, a study is conducted to compare the current unstructured transition (control group) to a structured transition (intervention group).

### What are the possible benefits and risks of participating?

The possible benefit is to experience a better transition based on case management. There are no risks.

### Where is the study run from?

The study is run from Hannover Medical School and supported by the German Pediatric Nephrology Association.

### When is the study starting and how long is it expected to run for?

April 2014 to March 2017

### Who is funding the study?

KfH Foundation for Preventive Medicine (KfH Stiftung Präventivmedizin) (Germany)

Who is the main contact?  
Prof. Lars Pape  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Lars Pape

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
TRANSNephro

## Study information

**Scientific Title**  
Rationale and design of the TRANSNephro study examining transition of post-kidney transplant adolescents: an analysis of present patient-centered care and multicenter randomized prospective open trial to test a new transition model using case-management and smartphone apps

**Acronym**  
TRANSNephro

**Study objectives**  
An introduction of a sustainable structured transition of adolescent nephrology patients from pediatric to adult care including smartphone apps and a case manager improves transplant survival.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics review board of Hannover Medical School, 06/04/2014, ref: 6660

**Study design**

Two-armed randomized prospective controlled interventional trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Kidney transplantation

**Interventions**

In phase I of the study, we are evaluating the patient transition situation in German nephrology departments, including an evaluation of the present situation in the view of physicians, nurses, and psycho-social support staff. In phase II, we will conduct a prospective, randomized study in which we compare current unstructured transition (control group) to structured transition (intervention group). The structured transition approach to be applied integrates the core elements of the Berlin transition program, which has not yet been established in German nephrology departments, in combination with two facilitating smartphone apps.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Variation coefficients for immunosuppressive agent levels, measured at the end of the study (1 year after transition)

**Secondary outcome measures**

1. Change in pre- and post-transfer estimated glomerular filtration rate (eGFR) (using the Schwartz 2009 formula, modification of diet in renal disease formula, and correction for cystatin-C levels)

2. Serum creatinine levels
3. Transplant survival
4. Patient survival
5. Acute rejection reactions (presence of donor-specific antibodies and chronic humoral rejection)
6. Transplant loss
7. Death
8. Patient satisfaction
9. Health care utilization
10. Patients self-reported quality of life and social integration

All outcomes will be measured at the end of the study (1 year after transition).

**Overall study start date**

01/05/2014

**Completion date**

31/03/2017

## **Eligibility**

**Key inclusion criteria**

1. Age 16-21 years
2. Kidney transplantation in history

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

100

**Key exclusion criteria**

Patients severely mentally retarded

**Date of first enrolment**

01/05/2014

**Date of final enrolment**

31/03/2017

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**  
**Hannover Medical School**  
Hannover  
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## **Sponsor information**

**Organisation**  
Hannover Clinical Trials Center (Germany)

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Carl-Neuberg-Straße 1  
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**Sponsor type**  
University/education

**Website**  
<http://www.clinical-trial-center.de/>

**ROR**  
<https://ror.org/040hkyv45>

## **Funder(s)**

**Funder type**  
Research organisation

**Funder Name**  
KfH Foundation for Preventive Medicine (KfH Stiftung Präventivmedizin) (Germany)

## **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="#">Protocol article</a>	protocol	23/12/2014		Yes	No
<a href="#">Results article</a>	results	12/06/2017		Yes	No
<a href="#">Results article</a>		03/04/2025	04/04/2025	Yes	No