

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

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

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

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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).

Completion date

31/03/2017

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

Germany

D-30625

Sponsor information

Organisation

Hannover Clinical Trials Center (Germany)

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

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?
Results article	results	12/06/2017		Yes	No
Results article		03/04/2025	04/04/2025	Yes	No
Protocol article	protocol	23/12/2014		Yes	No