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

Submission date
16/04/2014

Recruitment status
No longer recruiting

Registration date
25/04/2014

Overall study status
Completed

Last Edited
04/04/2025

Condition category
Urological and Genital Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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?
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Contact information

Type(s)
Scientific

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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
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Sponsor information

Organisation
Hannover Clinical Trials Center (Germany)

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