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Impaired graft survival of right kidneys from expanded criteria donors

Submission date
18/07/2024

Recruitment status
No longer recruiting

Registration date
19/07/2024

Overall study status
Completed

Last Edited
09/04/2025

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Transplantation of right kidneys is more challenging compared to left kidneys. Therefore, the aim of the study is to examine the effect of the donor side on the short- and long-term outcomes after primary kidney transplantation (KT).

Who can participate?
Patients aged 18 years and older who underwent initial living or deceased donor KT at the University Hospital of Leipzig between October 1995 and December 2015

What does the study involve?
The clinicopathological characteristics (signs, symptoms and results of lab tests), outcomes, and survival rates of the patients receiving primary KT were analyzed.

What are the possible benefits and risks of participating?
No patients underwent any new treatments or were exposed to any risks. The KT procedure and postoperative therapy (such as immunosuppression) were not modified for this study.

Where is the study run from?
University Hospital of Leipzig (Germany)

When is the study starting and how long is it expected to run for?
January 1995 to March 2024

Who is funding the study?
University Hospital of Leipzig (Germany)

Who is the main contact?
PD Dr Uwe Scheuermann, uwe.scheuermann@medizin.uni-leipzig.de

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
121255

Study information

Scientific Title
Outcome and survival of right kidneys

Study objectives
Transplantation of right kidneys is more challenging compared to left kidneys.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/04/2016, Ethikkommission an der Medizinischen Fakultät der Universität Leipzig (Liebigstraße 18, Leipzig, 04103, Germany; +49 (0)341 97 15490; ethik@medizin.uni-leipzig.de), ref: 111-16-14032016

Primary study design
Observational

Study design
Single-center retrospective cohort study

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Primary kidney transplantation

Interventions

Retrospective analysis of clinicopathological characteristics, outcomes, and survival rates of patients undergoing primary kidney transplantation between 1995 and 2015.

Standard statistical tests, including Student’s t-test, chi-squared test, analysis of variance (ANOVA), Kruskal–Wallis test, and Wilcoxon–Mann–Whitney test were used. Univariate and multivariate regression analyses were used to evaluate the risk factors of transplant outcome and survival.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Graft survival up to 10 years after kidney transplantation. Reasons and timepoint of graft loss are analysed. Graft failure was defined as a return to dialysis or preemptive re-transplantation.

Key secondary outcome(s)
1. Postoperative surgical complications (bleeding, vascular thrombosis, urine leak, wound infection, lymphoceles) up to 90 days after kidney transplantation
2. Renal function is measured using serum creatinine levels at baseline, 1 week, 2 weeks, 1 month, 3 months and 6 months after kidney transplantation
3. Patient survival rates up to 10 years after kidney transplantation. Reasons and timepoint of death are analysed.

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Adult patients (≥18 years of age) who underwent initial living or deceased donor kidney transplantation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
604

Key exclusion criteria
Multi-organ (combined) transplants or re-transplants

Date of first enrolment
01/01/1995

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital of Leipzig
Department of Visceral, Transplantation, Vascular and Thoracic Surgery
Liebigstrasse 20
Leipzig
Germany
04103

Sponsor information

Organisation
University Hospital Leipzig

ROR
https://ror.org/028hv5492

Funder(s)

Funder type
Government

Funder Name
Universität Leipzig

Alternative Name(s)

Leipzig University

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
The study database contains highly sensitive data which may provide insight into clinical and personal information about the patients and lead to the identification of these patients. Therefore, according to organizational restrictions and regulations these data cannot be made publicly available.
Repository: "Nephroton" database University Hospital Leipzig.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available