

Impaired graft survival of right kidneys from expanded criteria donors

Submission date 18/07/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/07/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/04/2025	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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?

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Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

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

Study design

Single-center retrospective cohort study

Primary study design

Observational

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**

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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