

# Impaired graft survival of right kidneys from expanded criteria donors

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<b>Registration date</b> 19/07/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/04/2025	<b>Condition category</b> 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?

PD Dr Uwe Scheuermann, [uwe.scheuermann@medizin.uni-leipzig.de](mailto:uwe.scheuermann@medizin.uni-leipzig.de)

## Contact information

Type(s)

Public, Scientific, Principal Investigator

**Contact name**

Dr Uwe Scheuermann

**ORCID ID**

<http://orcid.org/0000-0003-0859-9719>

**Contact details**

Liebigstrasse 20

Leipzig

Germany

04103

+49 (0)341/ 97-17200

[uwe.scheuermann@medizin.uni-leipzig.de](mailto:uwe.scheuermann@medizin.uni-leipzig.de)

## **Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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](mailto:ethik@medizin.uni-leipzig.de)), ref: 111-16-14032016

**Study design**

Single-center retrospective cohort study

**Primary study design**

Observational

## **Secondary study design**

Cohort study

## **Study setting(s)**

Hospital

## **Study type(s)**

Safety, Efficacy

## **Participant information sheet**

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

## **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 measure**

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.

## **Secondary outcome measures**

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.

## **Overall study start date**

01/01/1995

## **Completion date**

31/03/2024

## **Eligibility**

### **Key inclusion criteria**

Adult patients ( $\geq 18$  years of age) who underwent initial living or deceased donor kidney transplantation

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

100 Years

**Sex**

Both

**Target number of participants**

700

**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

**Sponsor details**

Liebigstrasse 20

Leipzig

Germany

04103

+49 (0)341/ 97-17200

chi2@medizin.uni-leipzig.de

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.uniklinikum-leipzig.de/>

**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**

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

**Intention to publish date**

01/08/2025

**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