

# TRABIO: registry for documenting treatment success after kidney transplant rejections

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/12/2020	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/04/2022	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Kidney transplantations are whenever possible the treatment of choice in end-stage renal (kidney) disease. However, acute and chronic rejections (when the body recognises the kidney as foreign tissue and attacks it) can limit the long-term outcome of the graft. This registry of TRAnsplant BIOpsies (TRABIO) aims to deepen the understanding of the distinct types of graft rejection and their treatment.

### Who can participate?

Adult kidney transplant patients with a medical indication for a kidney biopsy

### What does the study involve?

The registry is an observational cohort study, meaning that participation will not change anything about the treatment or diagnostics a patient receives (non-interventional). The results of the kidney biopsy and baseline medical data will be recorded and there will be a short-term follow-up as well as yearly long-term follow-ups for 5 years.

### What are the possible benefits and risks of participating?

There are no risks nor individual benefits in participating. Participation will eventually improve the scientific understanding of kidney graft rejections.

### Where is the study run from?

University Hospital Schleswig-Holstein (Germany)

### When is the study starting and how long is it expected to run for?

November 2015 to July 2032

### Who is funding the study?

Chiesi GmbH (Germany)

### Who is the main contact?

Dr Friedrich von Samson-Himmelstjerna  
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# Contact information

## Type(s)

Scientific

## Contact name

Dr Friedrich von Samson-Himmelstjerna

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## Contact details

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

B 278/16

# Study information

## Scientific Title

An observational, prospective, multi-center cohort study of kidney TRAnsplant BIOpsies (TRABIO) for graft rejections

## Acronym

TRABIO

## Study objectives

In spite of continued efforts, long-term kidney transplantation outcomes remain unsatisfactory. Acute and chronic kidney graft rejections are independent risk factors of graft failure, but evidence for the best treatment strategy is not clear. The TRABIO registry will address these uncertainties by providing data on short-and long-term outcomes after graft rejections.

## Ethics approval required

Old ethics approval format

## **Ethics approval(s)**

Approved 25/07/2016, ethics committee of the medical faculty of the Christian-Albrechts-University Kiel (Arnold-Heller-Str. 3, 24105 Kiel, Germany; no telephone number provided; ethikkomm@email.uni-kiel.de), ref: B 278/16

## **Study design**

Observational prospective multicenter cohort study

## **Primary study design**

Observational

## **Study type(s)**

Other

## **Health condition(s) or problem(s) studied**

Kidney biopsies for suspected acute and chronic rejections in patients with kidney grafts

## **Interventions**

In this observational, prospective cohort study, the researchers intend to enrol 800 kidney transplantation patients undergoing indication kidney biopsy in five transplantation centers across Germany. Baseline data (demography, medical history, immunosuppressive induction and maintenance medication, laboratory results) and detailed histopathology data will be entered into an electronic database upon enrollment. During the first follow-up (within 14 days) and consecutive yearly follow-ups (for up to 5 years), laboratory results, medication and the clinical course will be recorded. Patients will be stratified according to Banff-classification and treatment strategy, and influence on endpoints will be assessed using multivariate regression analysis.

## **Intervention Type**

Other

## **Primary outcome(s)**

Measured using patient records annually for 5 years:

1. All-cause mortality
2. Graft survival (defined as the absence of necessity for dialysis)

## **Key secondary outcome(s)**

Measured using patient records annually for 5 years:

1. Decline in kidney function ( $\geq 30\%$  decline of estimated glomerular filtration rate [eGFR] calculated from blood creatinine test, age, body size and gender; or new-onset large proteinuria with  $>300$  mg/dl on urine dipstick)
2. Recurrence of graft rejection

## **Completion date**

31/07/2032

## **Eligibility**

### **Key inclusion criteria**

1. Patients that have previously received a living- or deceased-donor kidney transplantation
2. Suspicion of graft rejection with a medical indication for a kidney biopsy
3. Male and female patients 18 years or older
4. Written, informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patient participates in an interventional trial
2. Previous known concerns regarding compliance
3. Pregnancy

**Date of first enrolment**

01/09/2016

**Date of final enrolment**

31/07/2026

**Locations****Countries of recruitment**

Germany

**Study participating centre**

**Universitätsklinikum Schleswig-Holstein**

Campus Kiel

Klinik für Innere Medizin IV

Arnold-Heller-Straße 3

Kiel

Germany

24105

**Study participating centre**

**Universitätsmedizin Mannheim**

V. Medizinische Klinik  
Theodor-Kutzer-Ufer 1-3  
Mannheim  
Germany  
68167

**Study participating centre****Universitätsmedizin der Johannes-Gutenberg-Universität Mainz**

Medizinische Klinik und Poliklinik  
Langenbeckstraße 1  
Mainz  
Germany  
55131

**Study participating centre****Universitätsklinikum Halle**

Universitätsklinik und Poliklinik für Innere Medizin II  
Ernst-Grube-Str. 40  
Halle (Saale)  
Germany  
06120

**Study participating centre****Klinikum Stuttgart**

Klinik für Nieren-, Hochdruck- und Autoimmunerkrankungen  
Kriegsbergstraße 60  
Stuttgart  
Germany  
70174

**Study participating centre****Klinikum rechts der Isar**

TU München  
Abteilung für Nephrologie  
Ismaninger Str. 22  
München  
Germany  
81675

**Sponsor information**

**Organisation**

Chiesi (Germany)

**ROR**

<https://ror.org/01zrbp537>

**Funder(s)****Funder type**

Industry

**Funder Name**

Chiesi GmbH

**Results and Publications****Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

**IPD sharing plan summary**

Other

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		21/04/2022	25/04/2022	Yes	No