

TRABIO: registry for documenting treatment success after kidney transplant rejections

Submission date 08/10/2020	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 16/12/2020	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 25/04/2022	Condition category 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?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

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?
Protocol article		21/04/2022	25/04/2022	Yes	No