TRABIO: registry for documenting treatment success after kidney transplant rejections

| Submission date | Recruitment status Recruiting | Prospectively registered | | |
|---------------------------|--|---|--|--|
| 08/10/2020 | | [X] Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 16/12/2020 Last Edited | Ongoing Condition category Urological and Genital Diseases | Results | | |
| | | Individual participant data | | |
| 25/04/2022 | | 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

Dr Friedrich von Samson-Himmelstjerna

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

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 measure

Measured using patient records annually for 5 years:

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

Secondary outcome measures

Measured using patient records annually for 5 years:

- 1. Decline in kidney function (≥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

Overall study start date

01/11/2015

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

800

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)

Sponsor details

Gasstraße 6 Hamburg Germany 22671 +49 (0)40 897 24-0 b.makenthun@chiesi.com

Sponsor type

Industry

Website

https://www.chiesi.de/

ROR

https://ror.org/01zrbp537

Funder(s)

Funder type

Industry

Funder Name

Chiesi GmbH

Results and Publications

Publication and dissemination plan

A protocol of the study design will be published (late 2020/at the beginning of 2021). A first publication summarizing the results of the 1-year follow-up data will be published in approximately 2023. Further publications reporting on the longer-term outcomes will follow at a later point.

Intention to publish date

31/07/2031

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 |