ISRCTN78772632 https://doi.org/10.1186/ISRCTN78772632

TRABIO: registry for documenting treatment success after kidney transplant rejections

Submission date
08/10/2020

Recruitment status
Recruiting

Registration date
16/12/2020

Overall study status
Ongoing

Last Edited
25/04/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
friedrich.vonsamson-himmelstjerna@uksh.de

Contact information

Type(s)
Scientific

Contact name
Dr Friedrich von Samson-Himmelstjerna

ORCID ID
https://orcid.org/0000-0002-4492-696X

Contact details
Department of Nephrology and Hypertension
University Hospital Schleswig-Holstein
Arnold-Heller-Str. 3 Haus C
Kiel
Germany
24105
+49 (0)431 500 23001
friedrich.vonsamson-himmelstjerna@uksh.de

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