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Kidney allograft protocol biopsy program

Submission date 03/11/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 20/11/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/03/2016	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
A biopsy is a procedure that involves taking a small sample of body tissue. It can be used to assess the functioning of a transplanted kidney (graft). A protocol biopsy is a biopsy taken at set intervals after transplantation. The aim of this study is to find out whether treating patients based on protocol biopsy findings improves the functioning and long-term survival of the transplanted kidney.

Who can participate?
Patients aged 18 or over who have received a kidney transplant

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in one group undergo a protocol biopsy 3 and/or 12 months after kidney transplantation, and based on the results receive appropriate treatment (e.g., steroids, drug dose reduction or withdrawal, antibiotics). Participants in the other group do not undergo a protocol biopsy and are treated based on clinical symptoms (if any occur). Kidney function and graft survival are assessed at 3 months after transplantation, then monthly until 12 months, then every 3 months until 10 years or graft loss.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Szeged (Hungary)

When is the study starting and how long is it expected to run for?
November 2002 to December 2016

Who is funding the study?
University of Szeged (Hungary)

Who is the main contact?
Dr Edit Szederkényi

Contact information

Type(s)
Scientific

Contact name
Dr Edit Szederkényi

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HU-SZTE-2205

Study information

Scientific Title
Role of protocol biopsy in preserving kidney allograft function: an open, randomised, controlled, single centre clinical trial

Acronym
ProBiRAF

Study objectives
Treatment of patients based on the protocol biopsy findings promotes preservation of the kidney allograft function, and therefore improves the long-term graft survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Investigation Review Board of the University of Szeged, Albert Szent-Györgyi Clinical Centre, 19/03/2002, ref: 2205

Study design
Open randomised controlled single-centre clinical trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Long-term graft survival

Interventions
Intervention: ultrasound-guided protocol biopsy 3 and/or 12 months after kidney transplantation. Based on the histology, appropriate treatment:
1. Steroid intravenous (i.v.) bolus
2. CNI dose reduction or withdrawal
3. Antibiotics

Control group: no protocol biopsy; treated based on clinical symptoms (if any occur).

10 years follow-up is planned, analysing data annually.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
1. Renal function measured by the serum creatinine and the estimated glomerular filtration rate (GFR)
2. Graft survival
3. Renal lesions measured by the Banff score

Time points:
Baseline, 3 months after transplantation, then monthly until 12 months, then every 3 months until 10 years or graft loss.

Secondary outcome measures
1. Proteinuria
2. Serum glucose
3. Total cholesterol
4. High density lipoprotein (HDL) cholesterol
5. Low density lipoprotein (LDL) cholesterol

6. Triglyceride
7. Blood pressure
8. Cardiovascular events (number of events)

Time points:
Baseline, 3 months after transplantation, then monthly until 12 months, then every 3 months until 10 years or graft loss.

Overall study start date
15/11/2002

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Adult patients (aged greater than 18 years), either sex
2. Receiving kidney transplant
3. A stable graft function (serum creatinine less than 300 µmol/l) three months after transplantation
4. No clinical symptoms or rejection for two months
5. Taking calcineurin-inhibitor (CNI) and mycophenolate mofetil (MMF) combination immunosuppressive therapy
6. A stable immunosuppressive drug trough level (tacrolimus [Tac] 5 - 15 ng/ml, cyclosporin [CsA] 100 - 250 ng/ml)
7. Signed informed consent, good compliance

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 patients per year (150 in total)

Key exclusion criteria
1. Rejection episode in the last two months
2. Taking anticoagulation therapy
3. Active infection

Date of first enrolment
15/11/2002

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Hungary

Study participating centre
Pécsi u. 6.
Szeged
Hungary
H-6720

Sponsor information

Organisation
University of Szeged (Hungary)

Sponsor details
Albert Szent-Györgyi Clinical Centre
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Sponsor type
University/education

Website
http://www.u-szeged.hu/indexe.html

ROR
https://ror.org/01pnej532

Funder(s)

Funder type
University/education

Funder Name
University of Szeged (Hungary) - Albert Szent-Györgyi Clinical Centre, Department of Clinical Surgery

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration