

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

Contact details

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Hungary
H-6720

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Open randomised controlled single-centre clinical trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration