

# Kidney allograft protocol biopsy program

<b>Submission date</b> 03/11/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/11/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/03/2016	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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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# 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

Department of Clinical Surgery

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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