

# Pre-treatment of deceased organ donors with methylprednisolone versus placebo for the prevention of post-ischemic acute renal transplant failure

**Submission date**

14/03/2006

**Recruitment status**

No longer recruiting

**Registration date**

12/04/2006

**Overall study status**

Completed

**Last Edited**

04/11/2010

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

**Study website**

<http://www.meduniwien.ac.at/nephrogene>

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Rainer Oberbauer

**Contact details**

Vienna Medical University

Waehringer Gürtel 18-20

Vienna

Austria

1090

+43 (0)140 400 4358

[rainer.oberbauer@meduniwien.ac.at](mailto:rainer.oberbauer@meduniwien.ac.at)

## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

P-18325

## **Study information**

**Scientific Title**

### **Study objectives**

Deceased organ donors exhibit a severe systemic inflammatory response caused by the brain death syndrome. This leads to an activation of inflammatory regulators in the donor kidney, associated with increased risk for subsequent development of post-ischemic acute renal transplant failure (ARTF) in the recipient. ARTF is the main risk factor for shortened allograft survival. Pre-treatment of deceased organ donors with corticosteroids before organ retrieval may modify the genome-wide gene expression in the donor kidney and thus reduce the incidence and duration of post-ischemic ARTF after engraftment.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved by the Ethics Committee of the Medical University Vienna on 14/03/2005, reference number: 067/2005

### **Study design**

Randomised placebo-controlled study

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Prevention

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Pre-treatment of deceased organ donors

### **Interventions**

The deceased organ donor will be randomized to receive 1000 mg of methylprednisolone or placebo three to six hours before organ retrieval. Donor kidney biopsies will be obtained before engraftment and genome-wide gene expression analysis will be performed using complementary deoxyribonucleic acid (cDNA) microarrays.

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Methylprednisolone

**Primary outcome measure**

Incidence and duration of post-ischemic acute renal transplant failure in the transplant recipient

**Secondary outcome measures**

Genome-wide gene expression analysis of transplant kidney wedge biopsies

**Overall study start date**

20/03/2006

**Completion date**

20/09/2008

**Eligibility****Key inclusion criteria**

Deceased kidney donors

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

200 deceased organ donors

**Key exclusion criteria**

Non-heart beating organ donors

**Date of first enrolment**

20/03/2006

**Date of final enrolment**

20/09/2008

## **Locations**

**Countries of recruitment**

Austria

**Study participating centre**

**Vienna Medical University**

Vienna

Austria

1090

## **Sponsor information**

**Organisation**

Austrian Science Fund

**Sponsor details**

Weyringergasse 35

Vienna

Austria

1040

+43 (0)1 505 67 40

office@fwf.ac.at

**Sponsor type**

Government

**Website**

<http://www.fwf.ac.at>

**ROR**

<https://ror.org/013tf3c58>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Austrian Science Funds (grant P-18325)

## 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

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 17/08/2010   |            | Yes            | No              |