

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

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised placebo-controlled study

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

Genome-wide gene expression analysis of transplant kidney wedge biopsies

Completion date

20/09/2008

Eligibility

Key inclusion criteria

Deceased kidney donors

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

ROR

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

Funder(s)

Funder type

Government

Funder Name

Austrian Science Funds (grant P-18325)

Results and Publications

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?
Results article	results	17/08/2010		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes