ISRCTN78828338 https://doi.org/10.1186/ISRCTN78828338

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

Registration date
12/04/2006

Last Edited
04/11/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

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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
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1090

Sponsor information

Organisation
Austrian Science Fund

Sponsor details
Weyringergasse 35
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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?
Results article	results	17/08/2010		Yes	No