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Second warm ischemia elimination in kidney transplantation

Submission date	Recruitment status	[_] Prospectively registered
06/06/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/06/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2023	Surgery	

Plain English summary of protocol

Background and study aims:
In a healthy person, the kidneys are responsible for filtering out the waste products and excess water in the blood, and converting them into urine. If the kidneys suddenly stop working (acute kidney injury) or are suffering from severe, long-term disease of the kidneys (chronic kidney failure) then the body is unable to get rid of the waste products building up in the blood. Eventually, the kidneys are no longer able to support the body's needs (end stage renal disease) and so a treatment to replace the work of the failed kidneys is needed. Kidney transplantation is the best treatment for end-stage renal disease. Kidneys harvested from deceased donors are already damaged before transplantation, both during storage (cold ischemia time) and the surgical procedure itself (warm ischemia time). There is currently a lack of information concerning the influence of warm and cold ischemia on kidney tissue. It is possible to eliminate warm ischemia using specially designed cooling system during kidney transplantation (ice bag technique, IBT). The aim of the study is to investigate whether elimination of warm ischemia will improve kidney allograft function and survival. The study will also assess the immune-related gene expression in kidney biopsy samples taken during transplantation.

Who can participate?
Adult kidney transplant candidates on an active waiting list for a new kidney who will have their surgery at Wroclaw Medical University Hospital.

What does the study involve?
Kidney recipients are randomly assigned to one of two groups. Those in the first group receive donor kidneys stored using the ice bag technique (IBT). This is in the form of a special bag, in which the kidney is placed in a central compartment with compartments of ice-cooled sterile saline (salt water) on either side, which is then placed on melting slushed ice. Those in the second group receive a kidney from the same donor, which is stored using the standard technique (no extra cooling). Participants in both groups attend follow up visits 7 days, 14 days, 1 month, 3 months, 6 months, 12, months, 18 months, 24 months and 60 months after their surgery in order for the functioning of the new kidney and any side effects to be assessed. In addition, for participants in both groups, three samples are taken of the transplanted kidney

immediately after the organ is recovered from the host, immediately before transplantation, and 30 minutes after the kidney has been transplanted in order to measure levels of immune system genes in the organ.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part, but there should be benefits to future transplant recipients if the study confirm that using ice bag technique improves the short- as well as long-term results of kidney transplantation. By taking part in this study there are no risks of physical injury or harm other than standard risk related to kidney transplantation procedure.

Where is the study run from?
Wroclaw Medical University Hospital

When is study starting and how long is it expected to run for?
August 2005 to December 2011

Who is funding the study?
The Polish Ministry of Science and Higher Education (Poland)

Who is the main contact?
Dr Dorota Kamińska
dorota.kaminska@umed.wroc.pl

Contact information

Type(s)
Scientific

Contact name
Dr Dorota Kamińska

ORCID ID
http://orcid.org/0000-0003-2400-9328

Contact details
Uniwersytecki Szpital Kliniczny we Wrocławiu
Borowska 213
Wrocław
Poland
50-556

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2 P05B 165 29

Study information

Scientific Title
Second warm ischemia elimination in kidney transplantation - structural and immunological changes in transplanted kidneys

Study objectives
Null hypothesis:
There will be no significant differences between the interventions with regards to graft function and survival, recipient function and survival, and intragraft immune-related gene expression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Commission of Bioethics at Wroclaw Medical University, 13/01/2005, ref: 36/2005

Study design
Single-centre randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Kidney transpantation

Interventions
Patients who fulfill the selection criteria and are willing to participate will be asked to complete a consent form, after reading a participant information leaflet. Treatment allocation is performed centrally at Department of Vascular, General and Transplant Surgery. The duration of participants in the trial is up to 60 months. All kidney allograft recipients were randomly assigned before transplantation to one of two groups

Group 1: Participants receive donor kidneys stored using the ice bag technique (IBT). This involves using a specially designed disposable polyethylene bag produced by Raguse GmbH

(Germany). The kidneys were prepared for implantation on the back table and put into a polyethylene bag in order to eliminate warm ischemia. The bag consisted of three compartments. The middle compartment homing the graft was surrounded by two external compartments filled with ice-cooled sterile saline and placed on the melting slushed ice. After placing the graft in the middle compartment the renal vein and artery were pulled outside the bag via a small hole in the middle compartment. Then the vascular renal vein and renal artery were anastomosed to the iliac vein and artery. After completion of the vascular anastomoses followed by graft reperfusion the polyethylene bag was removed from the transplanted kidney.

Group 2: Participants receive the contralateral kidneys from the same donorsusing the standard technique, which do not involve the extra cooling.

Except the use of IBT the pre- as well as post-transplant treatment do not differ between study groups. For both groups, during the transplantation procedure, three consecutive kidney core biopsies are obtained with a 16 G automatic needle (TSK Laboratory, Japan) at the following timepoints:
1. Immediately after organ recovery - biopsy 1 (B1)
2. After organ storage and cold ischemia, on the back table, before the transplantation procedure -biopsy 2 (B2)
3. Approximately 30 minutes after reperfusion -biopsy 3 (B3)

Participants in both groups attend follow up visits 7 days, 14 days, 1 month, 3 months, 6 months, 12, months, 18 months, 24 months and 60 months post-transplant. On each of these visits, the following clinical parameters are assessed: side-effects, graft survival, delayed graft function, rejection episodes, serum creatinine concentration, eGFR (estimated by MDRD formula), urine analysis, overall patient survival.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Graft function is determined by measuring eGFR (using MDRD formula) at 7 days, 14 days, 1, 3, 6, 12, 18, 24 and 60 months post-transplantation
2. Graft survival is measured through medical record review and patient urine output 7 days, 14 days, 1, 3, 6, 12, 18, 24 and 60 months post-transplantation
3. Delayed graft function rate is assessed through reviewing patient notes for dependence on haemodialysis at 7 days, 14 days, 1, 3, 6, 12, 18, 24 and 60 months post-transplantation
4. Rejection episode rate is determined through medical note review at 7 days, 14 days, 1, 3, 6, 12, 18, 24 and 60 months post-transplantation

Secondary outcome measures
Relationship between intragraft gene expression (B1,B2,B3) and post-transplant clinical parameters (patient and graft survival, graft function described as eGFR, delayed graft function and acute rejection episodes) are assessed at 7 days, 14 days, 1, 3, 6, 12, 18, 24 and 60 months post-transplantation

Overall study start date
23/08/2005

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Kidney transplant candidate on active waiting list assigned to transplantation in Wroclaw Medical University Hospital
2. Aged 18 years and over
3. Provision of written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
46

Key exclusion criteria
1. Decline participation in this study
2. Unable to comply with requirements of this study protocol

Date of first enrolment
10/09/2005

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Poland

Study participating centre
Wroclaw Medical University Hospital
Transplantation Center
Department of Vascular, General and Transplant Surgery and Department of Nephrology and Transplantation Medicine
Borowska 213
Wrocław

Poland
50-556

Sponsor information

Organisation
The Polish Ministry of Science and Higher Education

Sponsor details
20 Hoża Street
1/3 Wspólna Street
Warsaw
Poland
00-529

Sponsor type
Government

ROR
https://ror.org/05dwvd537

Funder(s)

Funder type
Government

Funder Name
The Polish Ministry of Science and Higher Education

Results and Publications

Publication and dissemination plan
Results were published as abstract:
1. Dorota Kamińska, Paweł Chudoba, Katarzyna Kościelska-Kasprzak, Agnieszka Lepiesza, Agnieszka Gomułkiewicz, Piotr Dzięgiel, Agnieszka Hałoń, Marian Klinger.: Gene expression in the deceased donor kidney determinates allograft function
Transpl.Int. 2015 Vol.28 suppl.4; s.158 poz.BO85
17th Congress of the European Society for Organ Transplantation. Brussels (Belgium), 13-16 September 2015.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/11/2016	10/07/2023	Yes	No