ISRCTN01577227 https://doi.org/10.1186/ISRCTN01577227

Effect of spironolactone on ischemia reperfusion injury in renal transplant recipients

Submission date
17/12/2012

Recruitment status
No longer recruiting

Registration date
23/01/2013

Overall study status
Completed

Last Edited
23/01/2013

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Ischemia and reperfusion processes are the major causes of acute kidney injury in patients receiving real tissues from a donor (this is called a renal allograft). This leads to different degrees of early post-transplant renal dysfunction. Aldosterone is a traditional treatment but has disadvantages. The aim of the study is to assess whether giving another drug called Spironolactone before and after renal transplant rom living donors decreases renal damage caused by ischemia/reperfusion

Who can participate?
You may participate if you are a patient in hemodialysis or peritoneal dialysis and you will receive a renal allograft from a living donor, you are at least 18 years old, you are male or female, you are compatible with your donor
You cannot enter this study if you receive two or more organs simultaneously and if you receive allograft from a deceased donor.

What does the study involve?
Participants will be randomly allocated to one of three groups of treatment (Spironolactone 50 mg, Spironolactone 100 mg or dummy). All treatments looks identical (1 capsule). Neither you nor your doctors will be able to know or decide which group you are in. You will take the capsule twice a day, three days before transplant surgery and five days after your surgery. The doctors will ask your permission to get a sample of blood and urine before transplant surgery and at days 1, 5 after transplant. They will use the samples to carry out routine laboratory tests in the laboratory that may help them to compare renal function recovery and biomarkers of renal injury. At day five after your surgery your participation will be completed.

What are the possible benefits and risks of participating?
The most common side effect of spironolactone is hyperkalemia (high level of serum potassium).

Where is the study run from?
This study will recruit 60 patients a year from the Transplant Department at Instituto Nacional de Ciencias Médicas Salvador Zubiran in México City, Hospital General de Mexico and Centro Médico Nacional Siglo XXI.

When is the study starting and how long is it expected to run for?
From January 2013 to .May 2014.

Who is funding the study?
Mexican Council of Science and Technology and National University of Mexico grants.

Who is the main contact?
Dr Luis E. Morales-Buenrostro
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
REF 421

Study information

Scientific Title
Effect of mineralocorticoid receptor blockade on ischemia / reperfusion injury in renal transplant recipients: A pilot study

Study objectives
Spironolactone reduces the tubular damage and oxidative stress in renal transplant patients from living donor.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of National Institute of Medical Sciences and Nutrition (Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubiran), January 2012, Ref 421

Study design
Double-blind randomized placebo-controlled clinical pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ischemia reperfusion injury

Interventions
The patients will be randomized to receive 50 or 100 mg of spironolactone (Sp) or placebo orally twice daily (BID), 3 days prior to transplant surgery and 50 or 100 mg of Sp or placebo orally BID during three consecutive days after transplantation.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Reduction of urinary biomarkers of kidney injury [Heat shock protein 72 (HsP72), Interleukin-18 (IL-18), kidney injury molecule-1 (KIM-1)] at baseline, day 1, and 5 post transplantation.

Key secondary outcome(s))
1. Reduction of oxidative stress
2. Change in urinary hydrogen peroxide excretion
3. Change in urinary nitrates excretion

All measures at baseline, day 1, and 5 post transplantation

Completion date
01/05/2014

Eligibility

Key inclusion criteria
1. Age of 18 years or older, male and female
2. Receipt of a live-donor kidney

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Multi-organ transplant
2. Deceased-donor kidney
3. Induction with thymoglobuline

Date of first enrolment
01/01/2013

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
Mexico

Study participating centre
Vasco de Quiroga no.
D.F
Mexico
14000

Sponsor information

Organisation
Mexican Council of Science and Technology (Consejo Nacional de Ciencia y Tecnología CONACyT) (Mexico)

ROR
https://ror.org/059ex5q34

Funder(s)

Funder type
Government

Funder Name
Health Sector Grant from Mexican Council of Science and Technology (Fondo Sectorial Salud 2012) (Mexico) Project: SALUD-2012-01-181267

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration