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Aldosterone blockade in children with chronic allograft nephropathy

Submission date	Recruitment status	[ ] Prospectively registered
09/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/06/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/09/2011	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

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
HIM/2009/015

Study information

Scientific Title
Aldosterone blockade in children with chronic allograft nephropathy: A prospective randomized controlled trial with patient blinding

Acronym
ABCWCAN (Efecto del Bloqueo de Aldosterona en la Nefropatía Crónica en Niños con Trasplante Renal)

Study objectives
Eplerenone prevents the progression of chronic allograft nephropathy in children

Ethics approval required
Old ethics approval format

Ethics approval(s)
The local research ethics committee (Comisión de Etica Hospital Infantil de México Federico Gómez) approved on the 16th f June 2009 (ref: HIM/2009/015)

Primary study design
Interventional

Study design
Prospective single blind randomized controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic allograft nephropathy

Interventions
Patients are randomized to receive Eplerenone to induce aldosterone blockade or a placebo. Visits scheduled at baseline, 1, 2, 4, 8, 12, 24 weeks and every three months afterwards to complete 2 years of follow-up.
A complete clinical examination is performed and blood sample is drawn for complete blood cell count, serum levels of creatinine, electrolytes, transaminases, cholesterol, tryglicerides. 24h urine collection for proteinuria and urine nitrates. Aldosterone and TGFb plasma levels will be measured every six months.

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome(s)
1. Change in glomerular filtration rate at 24 months

Key secondary outcome(s)
1. Acute rejection episodes in 24 months
2. Graft and patient loss

3. Adverse effects
4. Change in proteinuria
5. Change in urinaty nitrates excretion
6. Change in plasma levels of TGF-beta, aldosterone

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Patients aged 6 to 17 years within at least six months of receiving renal transplant
2. Patients with stable graft function defined as serum creatinine variation in the previous three months lower than 0.2 mg/dL
3. Chronic allograft nephropathy diagnosed by renal biopsy and Banff criteria
4. No evidence of acute rejection in the previous three months before enrolment
5. Glomerular filtration rate > 40 mL/min (Schwartz formula).
6. Serum potassium ≤ 5 mEq/L
7. Informed consent/assent properly signed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
17 Years

Sex
All

Key exclusion criteria
1. Acute graft rejection in the three months prior to enrolment
2. Serum creatinine variation in the previous three months > 0.2 mg/dL
3. Plasma Serum potassium > 5 mEq/L
4. Arterial hipotension
5. Patients receiving clarytromicin, calcium antagonists, itraconazol, fluconazol, erythromycin
6. Use of eplerenone 4 prior to enrolment

Date of first enrolment
01/06/2009

Date of final enrolment

30/06/2011

Locations

Countries of recruitment
Mexico

Study participating centre
Dr. Marquez 162
Mexico DF
Mexico
06720

Sponsor information

Organisation
Sectorial Fund for Health Research (Fondo Sectorial de Investigación en Salud) (Mexico)

Funder(s)

Funder type
Government

Funder Name
National Board of Science and Technology (Consejo Nacional de Ciencia y Tecnología) (Mexico) - Health Sector Fund 2008 (ref: 000000000087381)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration