

Aldosterone blockade in children with chronic allograft nephropathy

Submission date 09/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/06/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/09/2011	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 of June 2009 (ref: HIM/2009/015)

Study design

Prospective single blind randomized controlled study

Primary study design

Interventional

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 urinary 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 \leq 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 hypotension
5. Patients receiving clarytromycin, 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: 00000000087381)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration