

# Aldosterone blockade in children with chronic allograft nephropathy

<b>Submission date</b> 09/06/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/09/2011	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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)

## Study design

Prospective single blind randomized controlled study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

## 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 measure**

1. Change in glomerular filtration rate at 24 months

**Secondary outcome measures**

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

**Overall study start date**

01/06/2009

**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

**Age group**

Child

**Lower age limit**

6 Years

**Upper age limit**

17 Years

**Sex**

Both

**Target number of participants**

62

**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)

**Sponsor details**

Av. Insurgentes Sur no. 1582, 6° Piso

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Mexico DF

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03940

**Sponsor type**

Government

**Website**

<http://www.conacyt.mx/>

## **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**

**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