

# Efficacy and security of low toxicity immunosuppressive regimen using basiliximab, mycophenolate mofetil, neoral or tacrolimus and corticosteroids versus full doses of neoral, thymoglobulin, azathioprine and corticosteroids

<b>Submission date</b> 12/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/01/2008	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Domingo Hernandez

**Contact details**  
Nephrology Service  
Hospital Universitario de Canarias  
Ofra s/n La Laguna  
Tenerife  
Spain  
38320  
+34 922 678 545  
domingofernandez@gmail.com

## Additional identifiers

## Study information

Scientific Title

**Acronym**

Immuno99

**Study objectives**

To compare efficacy and security of low toxicity immunosuppressive regimen using basiliximab, mycophenolate mofetil (MMF), neoral (cyclosporin A [CsA]) or tacrolimus and corticosteroids versus full doses of neoral, thymoglobulin, azathioprine and corticosteroids.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approval received in May 1999 from two sources:

1. The Ethics Committee of the University Hospital of the Canary Islands (ref: Inmuno/99)
2. Agencia Española del Medicamento from Spanish Ministry of Health (ref: 99-0296)

**Study design**

Prospective, randomised, open-label, single centre, three parallel therapeutic armed trial.

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Kidney transplant

**Interventions**

Group one: thymoglobulin (1 to 1.5 mg/k/day for seven days), CsA (8 mg/k/day; levels: 175 to 225 ng/ml), azathioprine (1.5 mg/k/day) and corticosteroids

Group two: basiliximab (20 mg days zero and four), CsA (4 mg/k/day, levels: 125 to 175 ng/ml), MMF (2 g/day) and corticosteroids

Group three: basiliximab (20 mg days zero and four), tacrolimus (0.1 mg/k/day, levels: 8 to 12 ng/ml), MMF (2 g/day) and corticosteroids

**Intervention Type**

Drug

**Phase**

Not Specified

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

Basiliximab, mycophenolate mofetil (MMF), neoral (cyclosporin A [CsA]), tacrolimus, corticosteroids, thymoglobulin, azathioprine.

**Primary outcome(s)**

To determine renal function evaluated by calculated creatinine clearance at 6 and 12 months.

**Key secondary outcome(s)**

To assess acute rejection rate at 6 and 12 months, patient and graft survival rate at 12 months.

**Completion date**

21/03/2004

**Eligibility****Key inclusion criteria**

1. Aged over 18 years
2. Accepted informed consent
3. Primary kidney allograft
4. Cadaveric donor

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Panel Reactive Antibody (PRA) over 50%
2. History of malignancy
3. History of infection
4. Previous treatment with polyclonal antibodies or basiliximab

**Date of first enrolment**

27/10/1999

**Date of final enrolment**

21/03/2004

**Locations****Countries of recruitment**

Spain

**Study participating centre**

## Nephrology Service

Tenerife

Spain

38320

## Sponsor information

### Organisation

Hospital Universitario de Canarias (Spain)

### ROR

<https://ror.org/05qndj312>

## Funder(s)

### Funder type

University/education

### Funder Name

Foundation Rafael Clavijo, Research Unit, Hospital Universitario de Canarias (Spain)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	27/09/2007		Yes	No