# 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

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>Protocol</li></ul>		
12/09/2006				
Registration date	Overall study status	Statistical analysis plan		
04/01/2007	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
04/01/2008	Urological and Genital Diseases			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

# Protocol serial number

N/A

# 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

Fundation 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?
Results article	Results	27/09/2007		Yes	No