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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
12/09/2006

Recruitment status
No longer recruiting

Registration date
04/01/2007

Overall study status
Completed

Last Edited
04/01/2008

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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)

Primary study design
Interventional

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

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