ISRCTN87678078 https://doi.org/10.1186/ISRCTN87678078

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	Recruitment status	[_] Prospectively registered
12/09/2006	No longer recruiting	[_] Protocol
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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
27/10/1999

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

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)

Sponsor details
Fundation Rafael Clavijo
Research Unit
Ofra s/n La Laguna
Tenerife
Spain
38320
+34 922 678 545
domingohernandez@gmail.com

Sponsor type
Hospital/treatment centre

Website
http://www.hecit.es

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	27/09/2007		Yes	No