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Substitution of calcineurin inhibitors with sirolimus on left ventricular hypertrophy (LVH) of renal transplant recipients (RTR)

Submission date
28/04/2008

Recruitment status
No longer recruiting

Registration date
12/05/2008

Overall study status
Completed

Last Edited
25/02/2013

Condition category
Injury, Occupational Diseases, Poisoning

[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Substitution of calcineurin inhibitors (CNI) with sirolimus may regress left ventricular hypertrophy (LVH) of renal transplant recipients (RTR).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was not required as this trial complies with the recommendations issued by the ethical committee of the San Martino University Hospital (Azienda Ospedaliera Universitaria San Martino).

Study design
Non-randomised controlled trial.

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic allograft nephropathy in renal transplant recipients; left ventricular hypertrophy

Interventions
28 men and 14 women (total of 42 patients) were enrolled in this study.

All patients started CNI therapy. Subjects with chronic allograft nephropathy were switched to sirolimus, whereas patients not having chronic allograft nephropathy continued CNI and served as controls (non-randomised trial). The dose of sirolimus was titrated every other week in order to maintain trough levels between 5 and 15 mg/ml.

Duration of interventions: Interventions will continue as long as the participants require these immunosuppressants.

Total duration of follow-up: 12 months

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
calcineurin inhibitors, sirolimus

Primary outcome measure
Changes in left ventricular mass (LVMi) at 12 months

Secondary outcome measures
Changes in serum creatinine as a measure of graft function at 12 months

Overall study start date
01/06/2004

Completion date
31/01/2006

Eligibility

Key inclusion criteria
1. Age 25-66 years, both males and females
2. Non diabetic RTR with biopsy-proven chronic allograft nephropathy
3. Patients who have received a single kidney in 2004

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
42

Key exclusion criteria
1. Diabetic RTR
2. Patients receiving kidney transplant from living donors
3. Patients receiving dual kidney allograft

Date of first enrolment
01/06/2004

Date of final enrolment
31/01/2006

Locations

Countries of recruitment
Italy

Study participating centre
L.go R.Benzi 10
Genova
Italy
16132

Sponsor information

Organisation
San Martino University Hospital (Azienda Ospedaliera Universitaria San Martino) (Italy)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/04d7es448

Funder(s)

Funder type
Government

Funder Name
The Italian National Health Service (Servizio Sanitario Nazionale [SSN]) (Italy)

Funder Name
San Martino University Hospital (Azienda Ospedaliera Universitaria San Martino) (Italy)

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	01/09/2012		Yes	No