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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/04/2008		☐ Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
12/05/2008		[X] Results		
Last Edited		Individual participant data		
25/02/2013	Injury, Occupational Diseases, Poisoning			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

c/o Dr Giuseppe Cannella L. go R. Benzi 10 Genova Italy 16132

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