

# 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

Prospectively registered

Protocol

**Registration date**  
12/05/2008

**Overall study status**  
Completed

Statistical analysis plan

Results

**Last Edited**  
25/02/2013

**Condition category**  
Injury, Occupational Diseases, Poisoning

Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Giuseppe Cannella

### Contact details

L.go R.Benzi 10  
Genova  
Italy  
16132

## Additional identifiers

## 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

**Study type(s)**

Treatment

**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(s)**

Changes in left ventricular mass (LVMI) at 12 months

**Key secondary outcome(s)**

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

**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

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## 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)

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

### 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?
<a href="#">Results article</a>	results	01/09/2012		Yes	No