

# The use of the drug everolimus to reduce hypertrophy of the hearts left ventricle in kidney transplant recipients

<b>Submission date</b> 16/03/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/04/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/04/2011	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
n/a

## Study information

**Scientific Title**

The effect of the mammalian Target Of Rapamycin (mTOR) inhibitor everolimus on reducing left ventricular hypertrophy in renal transplant recipients (RTRs)

**Study objectives**

To investigate if mTOR everolimus induces regression of left ventricular hypertrophy (LVH) of renal transplant recipients (RTRs).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

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

**Study design**

Open-label randomised trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Non diabetic patients receiving kidney transplants

**Interventions**

1. Randomisation to either everolimus (EVL) plus reduced-exposure cyclosporine A (CsA) or standard-dose CsA
2. Anti-interleukin-2 receptor monoclonal antibodies for induction and steroids in both groups
3. Mycophenolate mofetil allowed in standard-dose CsA group
4. Antihypertensive therapy not including renin-angiotensin blocking agents allowed to achieve blood pressure (BP) of nearly 130/80 mmHg

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

mTOR everolimus

**Primary outcome measure**

Change in left ventricular mass index which is assessed by echocardiography after 1 year

**Secondary outcome measures**

1. Changes in renal graft function at one and three years
2. Incidence of acute rejection episodes at one and three years

**Overall study start date**

01/01/2008

**Completion date**

31/12/2009

## **Eligibility**

**Key inclusion criteria**

Non diabetic renal transplant recipients (RTRs)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

30

**Key exclusion criteria**

1. Patients receiving second transplant
2. Patients receiving dual transplant
3. Diabetic patients
4. Patients with severe cardiac valvular abnormalities

**Date of first enrolment**

01/01/2008

**Date of final enrolment**

31/12/2009

## **Locations**

**Countries of recruitment**

Italy

**Study participating centre**

**Largo R.Benzi 10**

Genova

Italy

16132

## Sponsor information

**Organisation**

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

**Sponsor details**

Largo R.Benzi

c/o Prof. Giuseppe Cannella

Genova

Italy

16132

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/04d7es448>

## Funder(s)

**Funder type**

Government

**Funder Name**

The Italian National Health Service (Servizio Sanitario Nazionale) (Italy)

**Funder Name**

San Martino University Hospital (Azienda Ospedaliera Universitaria San Martino), Genoa (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