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

Submission date 16/03/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/04/2011	**Overall study status** Completed	
Last Edited 08/04/2011	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
1. Changes in renal graft function at one and three years
2. Incidence of acute rejection episodes at one and three years

Completion date
31/12/2009

Eligibility

Key inclusion criteria
Non diabetic renal transplant recipients (RTRs)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration