ISRCTN93681079 https://doi.org/10.1186/ISRCTN93681079

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

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
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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