

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

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Contact details

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16132

Additional identifiers

Protocol serial number

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

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?
Results article	results	01/09/2012		Yes	No