Angiotensin Converting Enzyme (ACE) inhibitors in renal transplant recipients with left ventricular hypertrophy

Submission date	Recruitment status No longer recruiting	Prospectively registered		
15/03/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
29/03/2007	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
28/10/2022	Circulatory System			

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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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Angiotensin Converting Enzyme (ACE) inhibitors in renal transplant recipients with left ventricular hypertrophy

Study objectives

To test the effect of ACE inhibitors as compared to no therapy in regressing the left ventricular hypertrophy (LVH) that persisted longer following renal transplantation

Ethics approval required

Old ethics approval format

Ethics approval(s)

This trial did not require an ethical approval as the trial design was completely adherent to the recommendations issued by the local ethical committee Azienda Ospedaliera S. Martino (Genova, Italy) and in accordance to the guidelines issued by the Helsinki declaration.

Study design

Open-label randomized trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Left ventricular hypertrophy assessed by echocardiography in non diabetic chronic kidney disease patients receiving renal transplant

Interventions

Randomization to either ACE inhibitors or no therapy.

Conventional antihypertensive therapy allowed in order to achieve blood pressure (BP) nearly 130/80 mmHg

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

ACE inhibitors

Primary outcome(s)

Change in left ventricularymass index at 18 months

Key secondary outcome(s))

Cardiovascular events during follow-up

Completion date

Eligibility

Key inclusion criteria

Non diabetic renal transplant recipients with persisting LVH following successful renal transplant

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Total final enrolment

70

Key exclusion criteria

- 1. Subjects receiving second or dual transplant
- 2. Subjects with unstable renal graft function
- 3. Proteinuria > 1 g/ 24 hr
- 4. Congestive heart failure
- 5. Hemodinamically significant artery stenosis

Date of first enrolment

01/01/2001

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Italy

Study participating centre Divisione di Nefrologia, Dialisi e Trapianto

Genova Italy 16132

Sponsor information

Organisation

Azienda Ospedaliera Universitaria S.Martino (Italy)

ROR

https://ror.org/04d7es448

Funder(s)

Funder type

Government

Funder Name

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

Funder Name

Azienda Ospedaliera Universitaria S.Martino (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		01/07/2007		Yes	No