ISRCTN94487168 https://doi.org/10.1186/ISRCTN94487168

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

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

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

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 measure
Change in left ventricularvmass index at 18 months

Secondary outcome measures
Cardiovascular events during follow-up

Overall study start date
01/01/2001

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Non diabetic renal transplant recipients with persisting LVH following successful renal transplant

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
70

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
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Sponsor information

Organisation
Azienda Ospedaliera Universitaria S.Martino (Italy)

Sponsor details
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Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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