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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
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

Prof Giuseppe Cannella

#### Contact details

Divisione di Nefrologia, Dialisi e Trapianto Azienda Ospedaliera Universitaria S.Martino Genova Italy 16132

giuseppe.cannella@hsanmartino.it

# 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 ventricularymass 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 Italy 16132

# Sponsor information

## Organisation

Azienda Ospedaliera Universitaria S.Martino (Italy)

#### Sponsor details

c/o Prof Giuseppe Cannella L.go R.Benzi 10 Genova Italy 16132

## 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