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A randomised cross-over study comparing the effectiveness of bisoprolol and lisinopril in controlling hypertension after liver transplantation

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 21/07/2009	**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

Protocol serial number
N0544093459

Study information

Scientific Title

Study objectives
Bisoprolol versus lisinopril for hypertension after liver transplantation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled crossover trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiovascular: Hypertension

Interventions
Hypertension is common after liver transplantation and in Cambridge occurs in approximately 75% of patients. Treatment generally involves more than one drug but there have not been any studies comparing different antihypertensive medication. Thus optimal treatment of hypertension is not known. A cross-over study is planned to compare bisoprolol with lisinopril in patients with sustained hypertension after transplantation. Our current practice is to commence patients on amlodipine for hypertension. If this fails to control blood pressure then the dose is increased and patients are also commenced on a statin drug such as cerivastatin. Patients whose blood pressure is not controlled with amlodipine will then be randomised to receive either bisoprolol or lisinopril for 3 months, after which those taking bisoprolol will change to lisinopril and vice versa for a further 3 months. At this point the study ceases and the two treatments will be compared. Patients will be reviewed monthly in clinic to assess response to treatment and to allow for dosage adjustment where necessary. Measurements of plasma renin and arterial stiffness, using an ultrasound machine, will be collected during the study.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date

27/06/2003

Eligibility

Key inclusion criteria
40 Patients over 18 undergoing outpatient follow-up and having persisting hypertension.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
27/06/2000

Date of final enrolment
27/06/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Box No 157
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Other

Funder Name
Cambridge Consortium - Addenbrookes (UK)

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	15/03/2004		Yes	No