

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
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 21/07/2009	Condition category Circulatory System	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

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

Primary study design

Interventional

Study design

Randomised controlled crossover trial

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