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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
27/06/2000

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
40

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Other

Funder Name
Cambridge Consortium - Addenbrookes (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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