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Randomised controlled trial of carvedilol versus variceal band ligation in the primary prophylaxis of oesophageal variceal haemorrhage

Submission date 09/06/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/07/2007	**Overall study status** Completed	
Last Edited 21/09/2009	**Condition category** Digestive 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

LREC/1999/4/197

Study information

Scientific Title

Study objectives
Carvedilol, a vasodilating non-selective beta blocker is more effective than variceal band ligation in the prevention of the first variceal bleed in patients with high risk varices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval obtained from Lothian Research Ethics Committee on 14th February 2000.

Study design
Prospective multicentre randomised controlled clinical 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
Cirrhosis and portal hypertension

Interventions
1. Carvedilol starting at 6.25 mg per day for a week, to increase to 12.5 per day thereafter if tolerated
2. Variceal band ligation to be performed every two weeks until variceal eradication

The follow up periods for the carvedilol and banding arms are 23.3 ± 21.1 months and 22.1 ± 22.3 months respectively.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Carvedilol

Primary outcome measure
The first variceal bleed.

The outcomes were measured for the entire follow up period and also at 6, 12, and 24 months.

Secondary outcome measures
1. Overall mortality
2. Variceal bleeding related mortality
3. Adverse events leading to treatment discontinuation

The outcomes were measured for the entire follow up period and also at 6, 12, and 24 months. Bleeding induced mortality was defined as death within 6 weeks of the index variceal bleed.

Overall study start date
14/02/2000

Completion date
24/05/2006

Eligibility

Key inclusion criteria
Liver cirrhosis and the presence of Grade II or larger oesophageal varices.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
152

Key exclusion criteria
1. Aged less than 18 or greater than 75
2. Medication: vasoactive drugs such as beta blockers or nitrates
3. Advanced cardiopulmonary disease
4. Malignancy with prognosis that will affect study outcome
5. Allergy to carvedilol
6. Patients with obstructive airways disease

Date of first enrolment
14/02/2000

Date of final enrolment
24/05/2006

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Hepatology
Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation
University of Edinburgh (UK)

Sponsor details
Royal Infirmary
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Sponsor type
University/education

Website
http://www.ed.ac.uk/

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
University/education

Funder Name
University of Edinburgh (UK)

Alternative Name(s)
Universitas Academica Edinburgensis, Oilthigh Dhùn Èideann, The University of Edinburgh, University of Edinburgh in United Kingdom, Edin, Tounis College, King James' College, Athens of the North, ED, Edin

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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	01/09/2009		Yes	No