

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

<b>Submission date</b> 09/06/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/07/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/09/2009	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Peter Hayes

### Contact details

Department of Hepatology  
University of Edinburgh  
Little France  
Edinburgh  
United Kingdom  
EH16 4SA  
+44 (0)131 242 1625  
p.hayes@ed.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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  $23.3 \pm 21.1$  months and  $22.1 \pm 22.3$  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

Little France

Edinburgh

Scotland

United Kingdom

EH16 4SB

mvm@ed.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.ed.ac.uk/>

**ROR**

<https://ror.org/01nrxf90>

## **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?
<a href="#">Results article</a>	results	01/09/2009		Yes	No