

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
Registration date 05/07/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/09/2009	Condition category Digestive System	☐ 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

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.

Primary study design

Interventional

Study design

Prospective multicentre randomised controlled clinical trial

Study type(s)

Treatment

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(s)

The first variceal bleed.

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

United Kingdom

Scotland

Study participating centre

Department of Hepatology
Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation

University of Edinburgh (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

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