

Randomised controlled trial for the prevention of first variceal bleeding in cirrhotic patients with contraindications or intolerance to B-blockers (ligation versus no treatment)

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/09/2012	Condition category Circulatory 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0256111238

Study information

Scientific Title

Study objectives

Prophylactic banding in patients with contraindications to receive beta-blockers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Variceal bleeding

Interventions

A randomised controlled trial was designed, which will include cirrhotic patients with endoscopically documented varices and contraindications or intolerance to beta-blockers. Patients will be recruited during the outpatient clinic or on the wards. The enrolled patients will be randomised to receive prophylactic banding or no treatment. Patients randomised to banding will be banded weekly until total variceal obliteration is achieved at this point will have 3 monthly surveillance, as the usual practice. Patients will be asked to record all complaints. Patients randomised to no treatment will have their routine follow-up and yearly endoscopy. All patients should continued to be followed-up until at least 24 months.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

To compare in a randomised controlled trial whether endoscopic variceal ligation (EVL) therapy reduces the risk of first variceal bleeding compared to no-therapy and improves chances of survival in cirrhotic patients with contraindication or intolerance to B-blockers.

Secondary outcome measures

Not provided at time of registration

Overall study start date

12/12/1999

Completion date

15/06/2003

Eligibility

Key inclusion criteria

214 cirrhotic patients with contraindications to receive beta-blockers

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

214 patients (107 will receive prophylactic banding, 107 in control group)

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

12/12/1999

Date of final enrolment

15/06/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Liver Medicine/Transplantation

London

United Kingdom

NW3 2QG

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

Hospital/treatment centre

Funder Name

The Royal Free Hampstead NHS Trust. (UK) Own account

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	15/06/2005		Yes	No