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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

Registration date
12/09/2003

Last Edited
07/09/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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