

Variceal band ligation for primary prophylaxis

Submission date 12/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/05/2010	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 02/08/2016	Condition category Digestive System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

6427

Study information

Scientific Title

A multicentre randomised variceal band ligation for primary prophylaxis of oesophageal variceal bleeding in childhood portal hypertension

Study objectives

Prophylaxis banding for oesophagael varices has been performed in children who are deemed to be at risk of bleeding. There are very little data on the use of primary prophylaxis in childhood portal hypertension. Differences in underlying pathology and baseline bleeding rates suggest

that observations from adult practice should not be directly extrapolated to paediatric practice. At present there is no direct evidence to support universal primary prophylaxis for children with portal hypertension. The hypothesis is that prophylactic variceal band ligation will reduce the risk of variceal bleeding in children at significant risk of bleeding and the aim is to determine whether variceal band ligation is effective for preventing first variceal bleed in children with portal hypertension.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Midlands MREC, 26/01/2006, ref: 05/MRE07/76

Primary study design

Interventional

Study design

Multicentre randomised interventional prevention trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Gastrointestinal

Interventions

Children will be randomised to:

1. Prophylactic band ligation:

Ligation will be carried out under anaesthesia according to local practice using a multiband ligator. Bands will be applied to all variceal columns in the lower 5 cm of the oesophagus using up to a maximum of 6 bands. Sucralfate will be given four times a day (qds) for 5 days in age related dosing (less than 2 years, 250 mg; 2 - 12 years, 500 mg; greater than 12 years, 1 g). Other antacid treatment will be according to local practice.

Endoscopy will be repeated after 3 months and at 6 monthly intervals until all varices are ablated or decreased to small size. Subsequent surveillance endoscopy will be carried yearly. Recurrent varices will be treated with repeat ligation as above.

2. No prophylactic treatment:

Children will be reviewed clinically after 6, 12, 18 and 24 months. Endoscopic surveillance will be according to local practice.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Oesophageal variceal haemorrhage, defined as malena and/or haematemesis together with either:

1. Endoscopic visualization of blood emanating from oesophageal varices, or

2. The presence of varices together with blood in the stomach and no other source of identifiable bleeding

Key secondary outcome(s)

1. Other causes of gastrointestinal bleeding
2. Death due to variceal bleeding

Completion date

01/12/2010

Eligibility

Key inclusion criteria

1. Aged less than or equal to 16 years, either sex
2. Large oesophageal varices
3. No previous variceal bleed
4. Variceal band ligation feasible

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

16 Years

Sex

All

Key exclusion criteria

1. Previous endoscopic treatment for portal hypertension
2. Drug treatment for portal hypertension within previous 3 months
3. Anticipated need for liver transplantation or surgery for portal hypertension within 3 months
4. Presence of severe coagulopathy (international normalised ratio [INR] greater than 2.5 and/or platelets less than $50 \times 10^9/L$)

Date of first enrolment

01/03/2006

Date of final enrolment

01/12/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Birmingham Children's Hospital
Birmingham
United Kingdom
B4 6NH

Sponsor information

Organisation
British Society of Paediatric Gastroenterology Hepatology and Nutrition (BSPGHAN) (UK)

Funder(s)

Funder type
Charity

Funder Name
Children's Liver Disease Foundation (CLDF) (UK)

Alternative Name(s)
The Children's Liver Disease Foundation, CLDF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

