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# Variceal band ligation for primary prophylaxis

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

**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**
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

## Study design
Multicentre randomised interventional prevention trial

## Primary study design
Interventional

## 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 antiacid 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 x 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**

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |