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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please email Mrs Carla Lloyd at carla.lloyd@bch.nhs.uk to require a patient information sheet

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 measure
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

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

Overall study start date
01/03/2006

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

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned sample size: 200

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
England

United Kingdom

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)

Sponsor details
Administration Office
5 Woodthorpe Drive
Stourbridge
United Kingdom
DY9 7JX
-
administrator@bspghan.org.uk

Sponsor type
Research organisation

Website
http://bspghan.org.uk/

Funder(s)

Funder type
Charity

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

Alternative Name(s)
CLDF

Funding Body Type
Private sector organisation

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

Location
United Kingdom

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