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Carvedilol tablets compared with endoscopic banding treatment in preventing rebleeding from oesophgaeal varices

Submission date	Recruitment status	[_] Prospectively registered
19/11/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/12/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/10/2016	Digestive System	

Plain English summary of protocol

Background and study aims
In patients with chronic liver disease, rebleeding after a first variceal bleed (bleeding from the blood vessels in the oesophagus [food pipe] or stomach) is common, but is reduced by endoscopic therapy (band ligation) of the varices (dilated blood vessels). Initial studies have suggested that propranolol with or without isosorbide mononitrate tablets may be equally effective in reducing rebleeding and are cheaper and easier to take.
Recent data suggests that carvedilol tablets may be the best medical therapy to reduce the risk of variceal bleeding. Therefore our aim was to investigate whether oral carvedilol therapy was superior to standard endoscopic band ligation at preventing rebleeding following a first variceal bleed.

Who can participate?
We aim to recruit 152 patients, male or female, aged between 18 and 75 with a diagnosis of oesophageal variceal bleeding and cirrhosis.

What does the study involve?
Patients who are stable in hospital after a first variceal bleed will be invited to enter the study. Eligible patients who consent will be randomly allocated to receive either oral carvedilol (6.25 mg for one week, then 12.5 mg daily thereafter) or standard endoscopic band ligation of their varices. Patients will be followed up until 6 months after the last patient is allocated.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. However, there should be benefits to future patients because the results of the study are likely to influence how we treat similar patients in the future. The risks of carvedilol therapy are the same as those of any tablet which may reduce blood pressure, including dizziness or fainting.

Where is the study run from?
This multicentre study is being run from Glasgow Royal Infirmary. Patients will be recruited in Scotland, from Glasgow Royal Infirmary (the lead coordinating centre), the Royal Infirmary of Edinburgh, Gartnavel General Hospital Glasgow and the Southern General Hospital Glasgow.

When is the study starting and how long is it expected to run for?
The recruitment started in June 2006 and will run until the estimated number of patients has been recruited, which is expected to be end of 2013.

Who is funding the study?
Greater Glasgow & Clyde Health Board (UK).

Who is the main contact?
Dr Adrian Stanley
adrian.stanley@ggc.scot.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Adrian Stanley

Contact details
c/o GI Unit
Glasgow Royal Infrimary
Castle St
Glasgow
United Kingdom
G4 OSF
+44 141 211 4073
adrian.stanley@ggc.scot.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2006-000670-74

Protocol serial number
RN03GA006

Study information

Scientific Title
Multicentre randomised controlled study comparing carvedilol with endoscopic band ligation in the prevention of variceal rebleeding

Study objectives

The aim of this study is to investigate whether therapy with oral carvedilol tablets superior to endoscopic variceal band ligation in preventing rebleeding from varices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Glasgow Royal Infirmary North Glasgow NHS Trust Ethics Committee, 26/04/2004, ref: 03GA006

Study design
Randomised controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Variceal rebleeding in cirrhotic patients

Interventions
Oral carvedilol tablets versus endoscopic band ligation

Carvedilol is 6.25 mg once daily for one week and if tolerated then 12.5 mg once daily until the study is completed (6 months after the last patient is randomised)

Band ligation is done every 2-3 weeks until eradication then patient is endoscoped 6 monthly, with further bands applied as necessary.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Carvedilol

Primary outcome(s)
Variceal rebleeding is monitored when it occurs during follow-up. Patients will be followed up until 6 months after the last patient is randomised.

Key secondary outcome(s))
1. Mortality
2. Any upper gastointestinal bleeding is monitored when it occurs during follow-up

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Male or female aged ≥18 and <75yrs
2. Endoscopic diagnosis of oesophageal variceal bleeding
3. Cirrhosis (based on previous liver biopsy or clinical, biochemical and ultrasonographic findings)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Age <18 or >75 years
2. Advanced malignancy or another condition associated with a life expectancy of < 6/12 months
3. Previous transjugular intrahepatic portosystemic shunt (TIPS) or porto-caval shunt surgery
4. Portal vein thrombosis
5. Obstructive airways disease
6. Severe peripheral vascular disease
7. Heart block
8. Severe heart failure
9. Pregnancy
10. Type I diabetes mellitus
11. Gastric variceal bleed
12. Treatment with beta blockers or alpha blockers within 4 weeks of index bleed

Date of first enrolment
06/06/2006

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
United Kingdom

Study participating centre

c/o GI Unit
Glasgow
United Kingdom
G4 OSF

Sponsor information

Organisation
Greater Glasgow & Clyde (UK)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Greater Glasgow & Clyde Health Board (UK)

Results and Publications

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	01/11/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes