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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
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Adrian Stanley

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# Additional identifiers

### EudraCT/CTIS number
2006-000670-74

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure
Variceal rebleeding is monitored when it occurs during follow-up. Patients will be followed up until 6 months after the last patient is randomised.

### Secondary outcome measures
1. Mortality
2. Any upper gastointestinal bleeding is monitored when it occurs during follow-up

### Overall study start date
06/06/2006

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
152

### 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
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## Sponsor information

### Organisation
Greater Glasgow & Clyde (UK)

### Sponsor details
R&D Department
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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/05kdz4d87

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Greater Glasgow & Clyde Health Board (UK)

# 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 | 01/11/2014 | | Yes | No |