

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

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

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

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Contact details

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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

Primary study design

Interventional

Study design

Randomised controlled study

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 gastrointestinal 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 < 75 yrs
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