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Stent Oesophageal Varices: Effective haemostasis using self-expandable covered mesh-metal oesophageal stents versus standard endoscopic therapy in the emergency treatment of oesophageal variceal haemorrhage

Submission date 03/05/2013	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 03/05/2013	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 25/04/2019	**Condition category** Digestive System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Twice as many people now die from liver disease than in 1991, making liver disease the fifth big killer in England & Wales, with most deaths occurring in those under 60. Bleeding from veins in the gullet (Oesophageal varices) is one of the most serious complications of liver disease carrying a 1-in-5 risk of a patient dying. Current best treatments involve using medications to reduce bleeding and passing a camera, on the end of a narrow flexible tube called an endoscope, into the gullet to find the source of bleeding and stop it. Unfortunately the chances of this treatment failing to control the bleeding are about 1-in-4.

We are testing a device called a stent. This is a covered mesh-metal tube which is placed in the gullet using the endoscope. The stent expands to push on the walls of the gullet and stop the veins from bleeding.

Who can participate?

All patients who are admitted to participating hospitals with bleeding from veins in the gullet will be offered the opportunity to participate.

What does the study involve?

Participants will be randomly allocated to one of the two groups:

1. Oesophageal Stent
2. The best current treatments

This study will compare the new stent with the best current treatments

What are the possible benefits and risks of participating?

The stent as been used in a small number of patients and is currently reported to be 100%

successful at stopping bleeding. There are some minor complications, which can occur with the stent such as inflammation of the gullet, acid reflux from the stomach and very rarely perforation of the gullet. These will be discussed in full with all potential participants.

Where is the study run from?
The Co-ordinating centre is the Royal Free Hospital (UK)
There are 10 UK centres in total:
The Royal Free Hospital, London (Lead centre)
Bristol Royal Infirmary
The Royal London Hospital
Frimley Park Hospital, Surrey
Basildon & Thurrock University Hospitals
Royal Devon & Exeter Hospitals
Central Manchester University Hospitals
Royal Bournemouth Hospital, Dorset
Queen Alexandra Hospital, Portsmouth
University Hospitals Coventry & Warwickshire

When is the study starting and how long is it expected to run for?
The study is open now and will run until 2015.

Who is funding the study?
The study is being supported by a grant from ELLA CS (the company that make the stents), and by the National Institute of Health Research.

Who is the main contact?
Dr Brian Hogan
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01851564

Secondary identifying numbers
13392

Study information

Scientific Title
Effective haemostasis using self-expandable covered mesh-metal oesophageal stents versus standard endoscopic therapy in the emergency treatment of oesophageal variceal haemorrhage: A multicentre, open, prospective, randomised, controlled study

Acronym
SOV

Study objectives
The self-expanding oesophageal stent will:
1. Provide superior haemostasis and a reduction in failure to control bleeding when compared to standard endoscopic therapy
2. Be successfully implanted and well tolerated in >95% of the selected participants
3. Be associated with fewer minor side-effects for the participant (thoracic pain, dysphagia), and with earlier introduction of oral feeding when compared to standard endoscopic therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/LO/1873

Study design
Multicentre open prospective randomised controlled treatment 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
Topic: Blood, Oral and Gastrointestinal; Subtopic: Blood (all Subtopics), Oral and Gastrointestinal (all Subtopics); Disease: Non-malignant haematology, Hepatology

Interventions
Oesophageal Stent compared with the best current treatments

Oesophageal Stent, A self-expanding mesh metal removable oesophageal stent.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Failure to control bleeding (as defined by the Baveno V criteria) or re-bleeding within 7 days.

Secondary outcome measures
Not provided at time of registration

Overall study start date
22/08/2012

Completion date
31/08/2014

Eligibility

Key inclusion criteria
Arm 1:
Participants with Child-Pugh grade B or C cirrhosis with variceal haemorrhage, where the bleeding is from a site which would ordinarily be treated with band ligation (usually either oesophageal or GOV-1 varices). The diagnosis of cirrhosis may be proven by previous histology or suspected using clinical, radiological and biochemical data.

Arm 2: Participants with Child-Pugh grade A, B or C cirrhosis who present with failure to control bleeding within 5 days of an initial attempt at standard endoscopic therapy of acute haemorrhage from a site which would ordinarily be treated with band ligation (usually either oesophageal or GOV-1 varices).

Failure to control bleeding is demonstrated by the Baveno V criteria, either:

1. Fresh Haematemesis (or >100mls of fresh blood aspirated via NG >2 hours after therapeutic endoscopy)
2. Development of Hypovolaemic Shock
3. 3g drop in Haemoglobin within any 24 hours period if no transfusion is administered
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 136

Key exclusion criteria
1. < 18 Years of age
2. Child-Pugh grade A cirrhosis (Arm 1 only)
3. Non-cirrhotic portal hypertension
4. Malignancy of the oesophagus, stomach or upper respiratory tract
5. Oesophageal stenosis which prohibits endoscopy
6. Recent oesophageal surgery
7. A large hiatus hernia which prevents stent placement
8. Known hepatocellular carcinoma considered to be incurable (according to Milan Criteria).
9. Patients in the terminal phases of hepatological or other disease.
10. Pregnancy

Date of first enrolment
22/08/2012

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free Hospital
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
ELLA - CS, s.r.o.

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