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A controlled trial of terlipressin plus banding ligation versus terlipressin alone in the management of acute esophageal variceal bleeding

Submission date	Recruitment status	[_] Prospectively registered
18/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/03/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/09/2009	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Gin-Ho Lo

Contact details
386 Ta-Chung 1st Road
Kaohsiung
Taiwan
813
+886 (0)7 3422121/2075
ghlo@isca.vghks.gov.tw

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NSC 94-2314-B-075B-010

Study information

Scientific Title

Study objectives
The majority of patients with acute oesophageal variceal bleeding stop bleeding during endoscopy. It is still unknown whether endoscopic therapy is beneficial in those patients with acute inactive oesophageal variceal bleeding.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Veterans General Hospital Kaohsiung (VGHKS), reference number: 94-CT1-01

Study design
Randomised active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute oesophageal variceal bleeding but stopped bleeding during emergency endoscopy

Interventions
Group 1: terlipressin infusion for five days
Group 2: banding ligation performed during emergency endoscopy and terlipressin infusion for two days

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Terlipressin

Primary outcome measure
Initial control of variceal bleeding after 48 hours of treatment

Secondary outcome measures
Early rebleeding between 48-120 hours after treatment

Overall study start date
01/01/2005

Completion date
31/07/2007

Eligibility

Key inclusion criteria
1. Cirrhotic patients
2. Acute oesophageal variceal bleeding proven by emergency endoscopy within 12 hours

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Association with advanced hepatocellular carcinoma (HCC)
2. Association with other severe systemic illness
3. Association with gastric variceal bleeding
4. Previous shunt operation, endoscopic variceal ligation (EVL), beta-blocker or isosorbide mononitrate (ISMN) within one month
5. Serum bilirubin >10 mg/dl, creatinine >3 mg/dl
6. Presence of encephalopathy >grade 2
6. History of coronary artery disease
7. Uncooperative

Date of first enrolment
01/01/2005

Date of final enrolment
31/07/2007

Locations

Countries of recruitment
Taiwan

Study participating centre
386 Ta-Chung 1st Road
Kaohsiung
Taiwan
813

Sponsor information

Organisation
Republic of China National Science Council (Taiwan)

Sponsor details
106 Ho-Ping East Road
Section 2
Taipei
Taiwan
106
+886 (0)2 27377541
pihsu@vghks.gov.tw

Sponsor type
Government

ROR
https://ror.org/02kv4zf79

Funder(s)

Funder type
Government

Funder Name
Republic of China National Science Council (Taiwan)

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	01/09/2009		Yes	No