

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

**Submission date**

18/02/2006

**Recruitment status**

No longer recruiting

**Registration date**

30/03/2006

**Overall study status**

Completed

**Last Edited**

29/09/2009

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Protocol serial number**

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

**Primary study design**

Interventional

**Study design**

Randomised active controlled parallel group trial

**Study type(s)**

Treatment

**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(s)**

Initial control of variceal bleeding after 48 hours of treatment

**Key secondary outcome(s)**

Early rebleeding between 48-120 hours after treatment

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

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**Sponsor information**

**Organisation**

Republic of China National Science Council (Taiwan)

**ROR**

<https://ror.org/02kv4zf79>

**Funder(s)****Funder type**

Government

**Funder Name**

Republic of China National Science Council (Taiwan)

**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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/09/2009   |            | Yes            | No              |