

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

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| <b>Submission date</b><br>18/02/2006   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>30/03/2006 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>29/09/2009       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input checked="" type="checkbox"/> Results          |
|  |  | <input type="checkbox"/> Individual participant data |

**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**

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