

Can somatostatin control acute bleeding from oesophageal varices in *Schistosoma mansoni* patients?

Submission date 30/11/2004	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 01/12/2004	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 06/11/2019	Condition category Infections and Infestations	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Study information

Scientific Title

Can somatostatin control acute bleeding from oesophageal varices in *Schistosoma mansoni* patients?

Study objectives

Schistosomiasis is a disease causing liver fibrosis leading to portal hypertension and oesophageal varices that can cause fatal bleeding.

Given the background that somatostatin is an ideal vasoactive drug in the field of liver pathology, it is our opinion that somatostatin will be more efficacious and safe as compared to currently used beta blocker drugs like propranolol, in the control of acute oesophageal variceal bleeding due to Schistosoma mansoni infection. Moreover using this neuropeptide may increase time to failure of drug treatment, decrease incidences of early re-bleeding (day 4, 8) and incidences of death during the follow up period. Decreased frequencies of late rebleeding (days 30, 60, 90) may occur, all indicating the safety of using somatostatin. Praziquantel cover would be given to all study patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schistosomiasis

Interventions

Intervention: Intravenous (IV) infusion with somatostatin consisting of one bolus and infusion for 24 hours.

Control: Standard care, which is a beta blocker propranolol.

To study end results, questionnaires and sonography will be used.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Somatostatin, propranolol, praziquantel

Primary outcome(s)

The primary efficacy variable is the number of patients meeting the failure of therapy definition during the infusion period. Failure criteria are defined as death during infusion, persistence of active bleeding (The haemodynamic instability criteria points to the inability to achieve and maintain a systolic blood pressure of 80 mmHg OR presence of a 20 mmHg drop in systolic blood pressure from the highest post resuscitation value AND achieving a heart rate of 120 bpm OR a 20 bpm increase from highest post resuscitation value OR inability to achieve and maintain a Hct of 27% of Hb of 9 g/dl despite blood transfusion of 2 units or more.

The clinical criteria of active bleeding include hematemesis (fresh or semi fresh blood), hematochezia, melena.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2006

Eligibility

Key inclusion criteria

Schistosoma mansoni infected adolescent patients with variceal bleeding in the last 24 hours.

The inclusion criteria will be established fibrosis due to schistosomiasis of clinical history, physical examination and laboratory findings (and an examination compatible with the presence of portal hypertension due to fibrosis). Clinically active upper gastrointestinal bleeding (haematemesis of fresh or semi fresh blood and/or melena and/or haematochezia) with or without haemodynamic instability (systolic blood pressure < 80 mm Hg and heart rate > 120 bpm) will be selected. Subjects must be male or non-pregnant, non-lactating female subjects. Females of childbearing potential will have to utilize contraception for the duration of the study. Written or verbal documented informed consent will be needed from all subjects.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

Exclusion criteria will include participation by subjects in another investigational study within the last 14 days. Subjects may not undergo treatment with endotherapy, i.e. band ligation, sclerotherapy or other (balloon tamponade). Treatment with somatostatin, vasopressin or their analogues will also be a exclusion criteria. Subjects with end stage liver disease with hepatorenal syndrome, diffuse hepatocellular carcinoma, patent porto-systemic shunts, known diagnosis of non-fibrotic portal hypertension, severe cardiovascular diseases, i.e. acute myocardial infarction and heart failure will be excluded. Concurrent use of metoclopramide is also not advised.

Date of first enrolment

01/01/2006

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Belgium

Study participating centre

Head of Pathology

Antwerp

Belgium

B-2610

Sponsor information

Organisation

University of Antwerp (Belgium)

ROR

<https://ror.org/008x57b05>

Funder(s)

Funder type

Industry

Funder Name

External funding for this protocol comes from UCB-Pharma, Brussels, Belgium who have gifted the somatostatin (Belgium)

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?
Protocol article	Study protocol:	13/12/2004		Yes	No

