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

Submission date	Recruitment status	[X] Prospectively registered
30/11/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/12/2004	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/11/2019	Infections and Infestations	[_] 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

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 propanolol, 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

Study design
Randomised controlled trial

Primary study design
Interventional

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

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Somatostatin, propanolol, 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