Clinical Evaluation of Hemospray: Hemostasis of Active GI Lumincal Tract Bleeding (HALT)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal haemorrhages NEC
Study type	Interventional

Summary

ID

NL-OMON39250

Source
ToetsingOnline

Brief title
HALT (Hemostasis of Active GI Luminal Tract Bleeding)

Condition

- Gastrointestinal haemorrhages NEC

Synonym
bleeding peptic ulcers, nonvariceal GI bleeding

Research involving
Human

Sponsors and support

Primary sponsor: William Cook Europe, ApS
Source(s) of monetary or material Support: William Cook Europe (part of Cook Medical)

Intervention

Keyword: hemostasis, peptic ulcer

Outcome measures

Primary outcome

Primary effectiveness endpoint: Proportion of patients with further bleeds

within 72hours

of the index procedure

Secondary outcome

• Proportion of patients with hemostasis at conclusion of index procedure

(initial hemostasis)

• Clinical success: initial hemostasis and no SAE within 72 hours of index

procedure

• Early recurrent bleed: recurrent bleeding within 72 hours of the application

of Hemospray

• Late recurrent bleed: recurrent bleed occurring 72 hours - 30 days

• The incidence of serious adverse GI event within 30 days of the application

of Hemospray

• Incidence of serious adverse events within 30 days of the application of

Hemospray

• Incidence of mortality at 30 days

Study description

Background summary

Upper GI anatomy can be tortuous resulting in difficulty in applying current standard therapies which, with exception of argon plasma coagulation (APC), require direct tissue contact at the site of bleeding. Furthermore, the acidic environment of the stomach and duodenum present a challenge to the maintenance of hemostasis. Even in the presence of proton pump inhibitors (PPI) and/or histamine H2 receptor antagonists (H2 RA), naturally occurring clot can be broken down resulting in loss of longer term hemostasis. Therefore, spurting and oozing peptic ulcers may be considered the worst case scenario of GI bleeding due the challenging anatomy and environment. Evidence of device effectiveness in peptic ulcers with a high risk of recurrent bleeding (e.g., spurting, oozing ulcers) will be used to support the use of the Hemospray material in the GI tract.

A prospective, single arm, pilot clinical study of 20 patients was conducted at a single center in Hong Kong. The study was designed to evaluate the safety and effectiveness of Hemospray for hemostasis of active peptic ulcer bleeding (spurting or oozing).Twenty patients were recruited in this study (18 males, 2 females, mean age 60.2 years). Acute hemostasis was achieved in 95% (19/20) of patients; 1 patient in whom acute hemostasis was not achieved was treated with standard of care. After the failure of 3 subsequent attempts to gain hemostasis using epinephrine injection and hemostasis clips, the patient was referred for angiography. During angiopraphy, a pseudoaneurysm requiring arterial embolization was identified at the bleeding site. Of the 19 patients with successful acute hemostasis, sustained hemostasis was achieved in 17 (89.5%) patients through 72 hours. Two patients met the study definition of recurrent bleeding. One patient was found to have a drop in hemoglobin greater than 2 g/dL on Day 3 despite blood transfusion. Repeat endoscopy at 72 hours revealed no active bleeding. No further treatment was applied and the patient recovered uneventfully. The second patient developed tachycardia and hypotension with a drop in hemoglobin >2 g/dL on Day 2. Repeat endoscopy showed no active bleeding. In both of these patients, no active bleeding was observed at the treated lesion sites at the 72-hour second-look endoscopy indicating that the Hemospray maintained hemostasis at the treatment site. There was no mortality, no major adverse events and no treatment or procedure related serious adverse events reported during the 30-day follow-up. The results from this pilot study indicated that Hemospray is safe and effective for use in the GI tract.

Study objective

The goal of this investigation is to show that Hemospray is effective in achieving initial hemostasis rates equivalent to standard of care treatment and a decreased rate of further bleed when compared to standard of care up to 72 hours after treatment. In addition, this investigation will collect data regarding the ease of application and time to hemostasis which may show clinical advantage in the use of this single modality treatment.

Study design

This prospective, single-arm, open label study will evaluate the effectiveness of Hemospray for the hemostasis in patients with nonvariceal GI bleeding. The data collection may include up to 80 patients at up to 15 sites in the US, Europe, Canada and Hong Kong. The Hemospray treatment will be compared to a historical control using a performance goal based on a thorough literature review.

Intervention

Upon endoscopic verification of a bleeding peptic ulcer, Hemospray powder will be endoscopically applied to the bleeding ulcer until hemostasis is achieved, or until 3 syringes or 2 applications are exhausted. If hemostasis is not achieved using Hemospray, standard treatment will be used by the physician.

Study burden and risks

Despite being in contact with breached or compromised tissues, the Hemospray material appears to have no risk of systemic toxicity and showed no evidence irritation/intracutaneous reactivity when tested according to ISO10993-10 (NAMSA summary report).

There are risks including clinical or procedural complications that may develop as a result of endoscopic treatment with Hemospray. Endoscopic procedures are generally recognized as safe, but have known risks including but not limited to: perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, and cardiac arrhythmia or arrest. Applying Hemospray during an endoscopic procedure adds no additional risk to the endoscopic procedure. There are also clinical complications that may develop as a result of treatment with Hemospray. Although these risks are considered very unlikely, those classified as serious adverse GI events include: arterial embolization of the Hemospray and impaction of the Hemospray material in the colon.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients require hemostasis for nonvariceal GI bleeding. Specifically, patients with actively bleeding peptic ulcer with a Forrest score of 1a or 1b (spurting or oozing).

Exclusion criteria

• Patient is < 18 years of age
• Patient is unable or unwilling to provide written informed consent
• Patient is on a thienopyridine class antiplatelet agent (e.g., Clopidogrel, Ticlopidine and Prasugrel) which cannot be discontinued for the procedure and 72 hours post procedure
• Patient is pregnant or lactating
• Patient has uncorrected coagulopathy as determined by the physician
• Patient is contraindicated to undergo endoscopy
• Altered post surgical anatomy of the stomach (e.g., bariatric surgery)
• Patient has a previously placed intrahepatic portosystemic shunt
• Patient has an ASA class 5 (See Appendix D)
• Patients with gastrointestinal fistula (e.g., trachea-esophageal fistula, bronchio-esophageal fistula)
• Patient with suspected gastrointestinal perforation
• Patient has an INR > 2.5

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-07-2013
Enrollment:	13
Type:	Actual

Medical products/devices used

Generic name:	Hemospray
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-04-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-07-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-11-2014
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01306864
CCMO	NL37082.078.11