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Outcomes of patients with bleeding in the gastrointestinal tract, following treatment with Hemospray

Submission date	Recruitment status	[_] Prospectively registered
20/07/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/09/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/04/2021	Digestive System	

Plain English summary of protocol

Background and study aims
The treatment of gastrointestinal bleeding can be challenging. Endoscopy (the use of a tube with a camera to see inside the body) into the stomach can deliver treatment of the bleeding in the form of injections, clips and heat therapy. Hemospray is a white powder that can be sprayed onto the bleeding lesion via an endoscope to stop gastrointestinal bleeding through formation of a barrier. The aim of this project was to study the effectiveness of Hemospray to treat gastrointestinal bleeding.

Who can participate?
Adults with gastrointestinal bleeding

What does the study involve?
Patients with gasrointestinal bleeding will have an endoscopy procedure where they are treated with Hemospray to treat the bleeding, either alone or in combination with injections, clips or heat therapy. Hemospray is currently part of standard care for patients with gastrointestinal bleeding, and its use is at the discretion of the endoscopy doctor. There is no direct participation in this study for patients, as this study was completed through observation of the medical records of these patients.

What are the possible benefits and risks of participating?
There are no known benefits of participation in this study, as Hemospray treatment is standard care for gastrointestinal bleeding. There are no known risks of participating in this study, and the only risk Hemospray treatment itself carries is the potential for an allergic reaction.

Where is the study run from?
University College London Hospital, UK

When is the study starting and how long is it expected to run for?
January 2016 to January 2026

Who is funding the study?
This study is not funded, as Hemospray treatment is part of patient's standard of care and this study only involves observing the outcomes of this standard treatment

Who is the main contact?
Dr Rehan Haidry, Consultant Gastroenterologist, University College London Hospital (UCLH)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
n/a

Study information

Scientific Title
Outcomes from an international multi-centre registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray

Study objectives
Hemospray is effective in the management of gastrointestinal bleeding

Ethics approval required
Old ethics approval format

Ethics approval(s)
Presented to the London - South East Research Ethics Committee. The outcome was that the project would more appropriately be classified and managed as service evaluation and development rather than research, therefore no ethics approval is required.

Study design
Observational prospective multi-centre international registry

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gastrointestinal bleeding

Interventions
Participants were treated with Hemospray after endoscopic procedures as per routine clinical practice and their clinical records were observed for a 30 day period.

Intervention Type
Device

Primary outcome(s)
Endoscopic hemostasis of gastrointestinal bleeding when Hemospray is used on its own as monotherapy, dual therapy or rescue therap within 5 minutes of application of Hemospray.

Key secondary outcome(s))
The following are tracked over the 30 days of observation of hospital records:
1. Re-bleeding in less than 24 hours post initial endoscopy, at 24-72 hours, 4-7 days, 7-14 days and more than 14 days after the initial endoscopic therapy with Hemospray
2. 7 day and 30 day all-cause mortality
3. Baseline pathology and disease specific outcomes
4. Adverse events

Completion date
01/01/2026

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Gastrointestinal bleeding

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Key exclusion criteria
1. Allergic to Hemospray
2. Known perforation

Date of first enrolment
26/12/2016

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
United Kingdom

England

France

Germany

United States of America

Study participating centre
University College London Hospital
235 Euston Road
Fitzrovia
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
N/A

Funder(s)

Funder type

Not defined

Funder Name
None

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from Dr Durayd Alzoubaidi (d.alzoubaidi@ucl.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/06/2017		Yes	No
Results article		01/01/2020	19/04/2021	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes