ISRCTN29594250 https://doi.org/10.1186/ISRCTN29594250

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

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 20/07/2018 | Recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 05/09/2018 | Ongoing | [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)
rehan.haidry@nhs.net

### Study website
https://secure.amplitude-registry.com/EndoscopyRegistry

# Contact information

### Type(s)
Scientific

### Contact name
Dr Durayd Alzoubaidi

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Case series

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
The use of Hemospray is part of standard care of patients, therefore no participant sheet is available.

## 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 measure
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.

## Secondary outcome measures
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

## Overall study start date

01/01/2016

**Completion date**
01/01/2026

# Eligibility

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

**Participant type(s)**
Patient

**Age group**
Adult

**Lower age limit**
18 Years

**Sex**
Both

**Target number of participants**
10000

**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**
England

France

Germany

United Kingdom

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

**Sponsor details**
N/A
N/A
United Kingdom
N/A

**Sponsor type**
Not defined

**Website**
N/A

# Funder(s)

**Funder type**
Not defined

**Funder Name**
None

# Results and Publications

**Publication and dissemination plan**
Currently being considered for submission to Gastrointestinal Endoscopy (GIE).

**Intention to publish date**
01/10/2018

**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 |