ISRCTN40313068 https://doi.org/10.1186/ISRCTN40313068

A novel collagen-based dressing to use in bleeding wounds

Submission date
30/01/2026

Recruitment status
Not yet recruiting

Registration date
13/02/2026

Overall study status
Ongoing

Last Edited
22/06/2026

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The occurrence of everyday accidental injury at home or work, road traffic collisions, as well as assaults and acts of violence or terrorism are a routine occurrence throughout the world. In addition, at any one time, there are armed conflicts taking place. Major trauma and uncontrolled bleeding are very significant factors in causing death to people who have been injured. The availability of fast-acting products able to bring about rapid cessation of bleeding (haemostasis) can be a major factor in preventing unnecessary blood loss, infection and deaths.
CLOTTA™ is a collagen-based dressing designed to stop bleeding, and it has been used successfully in veterinary medicine for a while now. However, we need to prove that it is safe for use in humans before it can be made widely available for use. Therefore, we have designed this study to provide evidence that CLOTTA™ is both safe and effective in the emergency department of a hospital.

Who can participate?
All patients who present at the Emergency Department of the Queen Elizabeth Hospital will be screened to see if they are eligible to take part. They need to be over the age of 18 years and have a bleeding wound which requires a dressing to control the bleeding.

What does the study involve?
We will use the CLOTTA™ dressing on patients who agree to taking part in the study following information read to them by one of the trial team. We will then stay with the patient for 10 minutes and observe the CLOTTA™ dressing to see if there is evidence of bleeding through the dressing. If this happens, we will record the time after application. After the dressing is removed, we will check the area for any reactions and also ask the patient about how comfortable it was. Some data will be collected then the patient's participation in the study will be complete.

What are the possible benefits and risks of participating?
Collagen occurs naturally in the body, therefore the risks of use are low. However, it is possible that the patient may experience an allergic reaction because the dressing uses a poultry by-product. This is more likely if they have an existing allergy to meat products or eggs. As we are treating patients in a hospital with this dressing, any reaction like this can immediately be treated if it occurs.

We are unable to guarantee any direct benefit to participants that take part in this trial. Nonetheless, they will be contributing to an improved understanding of the control of bleeding wounds. The information gained from this trial will contribute to further studies and may help improve the treatment of people with similar injuries in the future.

Where is the study run from?
The Queen Elizabeth Hospital in Birmingham which is part of University Hospitals Birmingham NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2026 to August 2028

Who is funding the study?
Depletura Ltd, the company who makes the dressing

Who is the main contact?
1. Hazel Smith, hazel.smith@uhb.nhs.uk
2. Dr Sarafina Vatharkar, sarafina.vatharkar@uhb.nhs.uk

Contact information

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
325808

Study information

Scientific Title
A “first in human” clinical investigation study to determine the essential safety and performance of the CLOTTA™ haemostatic dressing in the control of actively bleeding wounds in trauma patients presenting to a Major Trauma Centre in the West Midlands

Acronym
CLOTTA

Study objectives
1. Safety as assessed by device related adverse events such as pain and local reactions
2. Performance assessed by time to haemostasis and occurrence of rebleeding (using the proxy of visual inspection of dressing)

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design

Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Patients with a single actively bleeding wound

Interventions
A sterile, off-white, collagen dressing measuring 10 cm x 7.5 cm and 0.8 cm depth, presented in an easy-open, sealed foil pouch. The dressing can be applied directly to bleeding wounds to initiate clot formation and bleeding cessation. The dressing will be used along with a standard pressure bandage to keep it in place, according to standard clinical practice and procedures.

No comparator is to be used.

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
CLOTTA

Primary outcome(s)
1. Cessation of bleeding measured using strike-through of trial dressing at up to 10 minutes

Key secondary outcome(s)

Completion date
31/08/2028

Eligibility

Key inclusion criteria

1. Patients attending the Emergency Department at the Queen Elizabeth University Hospital, Birmingham
2. Aged 18 years and over
3. All actively bleeding wounds which require application of a dressing
4. Isolated injury only (single wound)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 22/06/2026:

1. Known allergy to any meat products or eggs
2. Pregnancy (known or suspected)
3. “Code Red” patients (a critical, high level emergency medical response activated for patients with severe, life threatening bleeding due to major trauma)

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Previous key exclusion criteria:

1. Known allergy to any meat products or eggs
2. Pregnancy (known or apparent)
3. “Code Red” patients

Date of first enrolment
01/09/2026

Date of final enrolment
31/08/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
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Sponsor information

Organisation
Depletura Ltd

Funder(s)

Funder type

Funder Name
Depletura Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available