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Real-world evaluation of a novel, adhesion device for the prevention of post-operative bleeding

Submission date
20/06/2023

Recruitment status
No longer recruiting

Registration date
26/06/2023

Overall study status
Completed

Last Edited
13/11/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Haemostats are medical devices used by surgeons to stop bleeding during procedures and also to prevent bleeding restarting after the procedure has been completed. Not all haemostats stick to the bleeding site and so are less effective at preventing post-operative bleeding. Many of the haemostats that can adhere to the bleeding site use biological or chemical agents to achieve this. This study aims to evaluate a new haemostat (TenaTac) that avoids the use of biologic or chemical agents.

Who can participate?
Patients undergoing planned surgery at one of the participating hospitals if their surgeon is part of the evaluation group

What does the study involve?
During surgery, if the surgeon needs to use a haemostat and chooses to use TenaTac, then on completion of the surgery the surgeon will complete a structured questionnaire about how well the TenaTac performed.

What are the possible benefits and risks of participating?
The benefits are that the patient will avoid exposure to the biological or chemical agents used in alternative haemostats. The risks are that the TenaTac doesn't perform as well as another haemostat.

Where is the study run from?
St John's Innovation Centre, Cambridge, UK.

When is the study starting and how long is it expected to run for?
January 2020 to December 2025.

Who is funding the study?
The co-sponsors of the study are Selentus Science (UK) and CuraMedrix (Netherlands).

Who is the main contact?
Mr Paul Hayes MD FRCS, phayes@selentus.com

Contact information

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Public

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Additional identifiers

Protocol serial number
Cura PMCF 1

Study information

Scientific Title
Real-world, post-market clinical study of the intra-procedural performance of a novel adhesive haemostat across six surgical specialities

Study objectives
A novel adherent haemostat using only a simple physical modification of its surface would adhere adequately to tissues, and effect haemostasis on a bleeding surgical site to the satisfaction of the operating surgeon.

Ethics approval required
Ethics approval not required

Ethics approval(s)
The study is a post-market clinical follow up of a CE-marked medial device being used within its Indication for Use. The choice of which haemostat to treat the patient with was at the discretion of the surgeon and no mandating of treatment occurred. No patient data was shared, only information relating to the general type of surgery and the performance of the device.

Primary study design
Observational

Study design
Observational case series

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of haemorrhage in surgical patients

Interventions
A novel haemostat using only a physical modification of the device surface to affect adhesion was evaluated by multiple surgeons, across 6 surgical specialities. A structured questionnaire relating to the device performance was completed by the surgeon at the end of the procedure.

The application of a haemostat to the bleeding site. No control agent is planned. The adherence of the haemostat to the tissue surface will be graded 1 to 5 by the surgeon, as will the efficacy of haemostasis obtained.

Intervention Type
Device

Phase

Not Applicable

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

Primary outcome(s)
The effectiveness of haemostasis graded from 1 (unacceptable) to 5 (excellent) by the operating surgeon at the end of the procedure.

Key secondary outcome(s)
1. The effectiveness of adhesion graded from 1 (unacceptable) to 5 (excellent) by the operating surgeon at the end of the procedure.
2. The ease of use of the haemostat graded from 1 (unacceptable) to 5 (excellent) by the operating surgeon at the end of the procedure.
3. Binary response to whether the surgeon would use the product again during surgery

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Patient undergoing elective surgery
2. Patient greater than 16 years of age
3. Able to give informed consent
4. Willing to complete study procedures and attend for follow-up visit

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Presence of a documented disorder of coagulation
2. An INR >2.0 within 12h of surgery (if measured)
3. Allergy to porcine products
4. Use of dual anti-platelets within 3 days of surgery
5. Oral anti-coagulant use within 24h of surgery
6. Enrolment in another clinical study that might reasonably interfere with this study's end-points
7. Member of a vulnerable group of adults or life expectancy less than one year.

Date of first enrolment
14/01/2020

Date of final enrolment
01/11/2025

Locations

Countries of recruitment
United Kingdom

England

Belgium

Croatia

Denmark

France

Germany

Netherlands

Serbia

Sweden

Study participating centre
St John's Innovation Centre
Cowley Road
Cambridge
England
CB4 0WS

Study participating centre

Dept of Neurosurgery
Antwerp University Hospital (UZA)
Antwerp
Belgium
2650

Sponsor information

Organisation
Selentus Science

Funder(s)

Funder type
Industry

Funder Name
Selentus Science

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available