ISRCTN54521345 https://doi.org/10.1186/ISRCTN54521345

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

Submission date
20/06/2023

Recruitment status
Recruiting

Registration date
26/06/2023

Overall study status
Ongoing

Last Edited
23/06/2023

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

Type(s)
Public

Contact name
Mr Paul Hayes

ORCID ID
https://orcid.org/0000-0002-1968-5930

Contact details
BioCity, 1 Thoresby Street
Nottingham
United Kingdom
NG1 1GF
+44 1159124210
enquiry@selentus.com

Type(s)
Scientific

Contact name
Mr Paul Hayes

Contact details
Biocity, 1 Thoresby Street
Nottingham
United Kingdom
NG1 1GF
+44 1159124210
phayes@selentus.com

Type(s)
Principal Investigator

Contact name
Mr Paul Hayes

Contact details
BioCity, 1 Thoresby Street,
Nottingham
United Kingdom
NG1 1GF
+44 1159124210
phayes@selentus.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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.

Study design
Observational case series

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

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

Secondary outcome measures
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

Overall study start date
01/10/2021

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

Age group
Adult

Lower age limit
16 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
300

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
Belgium

Croatia

Denmark

England

France

Germany

Netherlands

Serbia

Sweden

United Kingdom

Study participating centre
Thoracic and Vascular Dept
University Hospital Ghent
Ghent
Belgium
9000

Study participating centre
Clinic for Cardiothoracic Surgery
Military Medical Academy
Belgrade
Serbia
11050

Study participating centre
Oder-Spree Krankenhaus GmbH
Schützenstrasse 28
Beeskow
Germany
15848

Study participating centre
Dept of Neurosurgery
Antwerp University Hospital (UZA)
Antwerp
Belgium
2650

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

Study participating centre
Plastic and Aesthetic Surgery
University Hospital
University of Cologne
Cologne
Germany
50937

Sponsor information

Organisation
Selentus Science

Sponsor details
Biocity, 1 Thoresby Street
Nottingham
England
United Kingdom
NG1 1GF
+44 1159124210
enquiry@selentus.com

Sponsor type
Industry

Website
https://www.selentus.com/

Funder(s)

Funder type
Industry

Funder Name
Selentus Science

Results and Publications

Publication and dissemination plan
As this is a novel device we plan to evaluate the data after 20%, 50% and 100% of the cohort has been recruited. The results will then be published in a peer-reviewed journal

Intention to publish date
01/07/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to commercial sensitivity

IPD sharing plan summary
Not expected to be made available