PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Intraoperative bleeding control with thrombin-gelatin-matrix (Floseal) in advanced gynecologic surgery. A case-control study with special focus on hemostasis in patients with primary or secondary coagulapathies.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Intraoperative and postoperative bleeding control is a major challenge in advanced gynaecologic surgery. For instance, excessive bleeding (more than 1 L) complicates 30-40% of radical oncologic operations. It results in prolonged operation and hospitalisation times, increases the frequency of re-operations and blood transfusions, and at least it increases the direct or indirect therapy costs. The haemostatic thrombin-gelatin-matrix Floseal® (Baxter) is registered for supporting the local haemostasis “when control of bleeding by ligature or conventional procedures is ineffective or impractical”. The haemostatic matrix Floseal® is well known e.g. in the visceral surgery or in neurosurgery. It enhances the local clot building at the bleeding site, without impacting the systemic haemostasis. Unfortunately, it is still not well known in the gynaecologic surgery. Raga et al. (1999) describes the largest patient sample (25 cases vs. 25 controls) so far. There exist also some encouraging case reports about successfully application of the haemostatic matrix for reducing blood loss in the gynaecologic and obstetrical surgery. We aim a retrospective comparison of 70 patients (with intraoperative application of Floseal®) and 130 controls (without intraoperative application of Floseal®) according to several outcome measures (e.g. blood loss, transfusions, length of hospital stay).

Brief Summary in Scientific Language

Intraoperative and postoperative bleeding control is a major challenge in advanced gynaecologic surgery. For instance, excessive bleeding (more than 1 L) complicates 30-40% of radical oncologic operations. It results in prolonged operation and hospitalisation times, increases the frequency of re-operations and blood transfusions, and at least it increases the direct or indirect therapy costs. The haemostatic thrombin-gelatin-matrix Floseal® (Baxter) is registered for supporting the local haemostasis “when control of bleeding by ligature or conventional procedures is ineffective or impractical”. The haemostatic matrix Floseal® is well known e.g. in the visceral surgery or in neurosurgery. It enhances the local clot building at the bleeding site, without impacting the systemic haemostasis. Unfortunately, it is still not well known in the gynaecologic surgery.

Raga et al. (1999) describes the largest patient sample (25 cases vs. 25 controls) so far. There exist also some encouraging case reports about successfully application of the haemostatic matrix for reducing blood loss in the gynaecologic and obstetrical surgery (e.g. Ebert et al. 2009; Angioli et al. 2009). We aim a retrospective comparison of 70 patients (with intraoperative application of Floseal®) and 130 controls (without intraoperative application of Floseal®) according to several outcome measures (e.g. blood loss, transfusions, length of hospital stay).

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004903**
- Date of Registration in DRKS: **2013/05/06**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **194/12 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1141-9266**

Health condition or Problem studied

- ICD10: **D62 - Acute posthaemorrhagic anaemia**
- ICD10: **T81.0 - Haemorrhage and haematoma complicating a procedure, not elsewhere classified**

Interventions/Observational Groups

- Arm 1: **Patients with intraoperative bleeding WITH application of the thrombin-gelatin matrix (Floseal®, Baxter). Retrospective data collection on blood loss and inflammatory response, need for transfusions, duration of surgery, duration of hospital- and ICU stay, need for re-operations.**
- Arm 2: **Patients with intraoperative bleeding WITHOUT application of the thrombin-gelatin matrix. Comparison of the parameters (as above) in patients**

who had similar operations in the same period.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Other**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Intraoperative blood loss. Evaluation of postoperative Hb-drop and need for transfusions.

Secondary Outcome

Duration of surgery, hospital stay and ICU stay in patients with and without Floseal use.
Comparison of the inflammatory response by maximum postoperative CRP increase.
Comparison of revision surgeries in patients with and without Floseal use.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **St. Josefskrankenhaus, Lehrkrankenhaus der Universität Freiburg, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/05/11**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2012/05/11**

- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1. Intraoperative bleeding with actual or anticipated blood loss> 1 liter
2. Extensive suergery defined as: "basic operation" (eg, hysterectomy) plus at least one of the following steps: a) lymphadenectomy, b) retropertitoneal preparation, c) peritonectomy, d) operative haemostasis in parenchymal organs
3. Alternative to item 2: Acute bleeding complications requiring operative revision
4. Application only in accordance with the instructions and within the indication

Exclusion criteria

One of the inclusion criteria not fulfilled

Addresses

- **Primary Sponsor**

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  Sautierstr. 1

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■ **Collaborator, Other Address**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*