Title:

Studying Hemostatic Effect of Axiostat Dressing on Radial Access After Percutaneous Procedure (AHD)

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Protocol

Studying Hemostatic Effect of Axiostat® Dressing on Radial Access After Percutaneous Procedure (AHD)

Purpose

To evaluate Safety and Efficacy of Axiostat haemostatic dressing in terms of time to achieve immediate haemostasis, post application complication and comfort levels of patients.

Type of Study

Single Arm, Single Centre, Prospective

Study Population

Patients who undergo trans radial diagnostic or interventional cardiac procedures and who meet all eligibility criteria will be approached for participation in the study.

Inclusion Criteria

1. Age greater than or equal to 18 years.
2. Patient and/or patient's legal representative and/or impartial witness has/have been informed of the nature of the study and agrees to its provision and has provided written informed consent as approved by the Ethics Committee of the investigative site.
3. Iatrogenic puncture
4. Patient who want to undergo radial intervention.
5. All puncture size must be less than 2.5cm.

Exclusion Criteria

1. Prior diagnosis of disease or medical condition affecting the ability of blood to clot (e.g., hemophilia.).
2. Patients with known sensitivity to chitosan (shellfish) used in this study.
3. Patients who, in the opinion of the Investigator, may not complete the study for any reason, e.g. Patient requiring Immediate suturing.
4. Patient is currently participating in an investigational drug or dressing study that has not yet completed its primary endpoint interferes with procedure and assessments in this study.
5. Pregnant women.
6. Patients with hemorrhagic shock.
7. Patient having hemoglobin < 9 g/dl.

Primary Outcome

Time to achieve hemostasis by observing the time at which blood oozing through or from periphery of the dressing stops.

Secondary Outcomes

(i) Number of patients with rebleeding will be counted
(ii) Quantity of product used
(iii) Skin Irritation and Hematoma formation
(iv) Ease of use of Product
(v) Patient Comfort Levels

Materials and Methods:

Study Material

Axiostat® - Size: 3.5 cm X 3.5 cm

Axiostat Chitosan Hemostatic dressing belongs to an advanced class of wound dressing that stops bleeding within few minutes of application by providing an active mechanical barrier.

The dressing is approved in Europe (CE Certified) for the closure of arterial access sites and will be used in this study according to the approved application.

Screening Evaluation & Enrolment

Each potential subject who meets the protocol inclusion and exclusion criteria will be given a description of the study dressing, informed about the goals, risks-benefits and then invited to voluntarily participate in the study. Investigator will answer all the questions asked by patient and/or patient's representative. If a patient/patient's representative or impartial witness voluntarily agrees to participate in the study, he/she will read, understand, sign and date the informed consent form prior to the initiation of any study procedure. Each subject is free to withdraw from the study at any time during the study period.

Application of Axiostat

Inspect the puncture site to assess for inclusion in the study.
Make Sure to wear gloves
Open the dressing pack carefully (Axiostat tends to stick with blood on gloves)

- Remove the sheath and apply Axiostat along with the cotton gauze. Allow blood about 1 or 2 ml of blood to come in contact with Axiostat.
- Make sure Axiostat is placed directly above the puncture site.
- Apply pressure with fingers for about 5 minutes until dressing adheres to blood on puncture site and stays in position.
- Apply secondary dressing (as per Institutional care) such as Dynaplast Bandage. Do not remove or move Axiostat from position during this procedure and keep Axiostat in position for at least 30 minutes.
- If bleeding is persistent, then remove the first Axiostat and apply another Axiostat, on puncture bleeding site. Repeat the same procedure of treatment application.
- Failure to achieve haemostasis after two applications will be noted as dressing failure. In case of dressing failure, patient will be treated as per institutional standard of care.

Time, at which blood oozing through or from periphery of the dressing stops, will be considered as achieving haemostasis and will be noted as the efficacy endpoint.

Axiostat can be kept on site for 24 hours.
Removal of Axiostat: Axiostat must be removed by irrigating it with saline solution / water and gently lifting it off.
Patients will be followed up till discharge.

Training: Training will be rendered to four catheterization laboratory (cathlab) operators for application and direction of use of Axiostat as per study protocol.

Adverse Event Reporting

Investigators shall report all adverse events on the Adverse Event Report Form. All Serious Adverse Event (SAE) need to be reported to the sponsor within 24 hours after the investigator becomes aware of the event. SAE reporting will be done using the Event Reporting Form.
All adverse events need to be reported in the Adverse Event Report Form till patient discharge from hospital for the procedure, if any. Ethics Committee (EC) will be notified for any occurrence of SAE as required per local regulations. Sponsor will be responsible to notify any occurrence of SAE to competent authorities, if applicable

Sample Size

From available literature [1], with the assumption that Axiostat® will decrease time to haemostasis by 30%, minimum number of patients needed for study (with alpha 0.05 and power 0.8) was 15 patients. A total of 75 patients will recruited, with drop-out rate of 10%, ~ 67 patients will be included in the study

Statistical Analysis Plan

Pearson correlation analysis will be performed to check the co-relation between primary efficacy endpoint. Independent sample t-test will be performed to compare the mean of hemostasis time between independent categorical variables. A P-value of ≤ 0.05 will be considered to be significant. Secondary endpoint will be analyzed by descriptive statistics.

References:

1. Arbel J, Rozenbaum E, Reges O, Neuman Y, Levi A, Erel J, Haskia AR, et al. Usage of chitosan for femoral (USF) hemostasis after percutaneous procedures: a comparative open-label study. Euro intervention. 2010; 6:1-6. 1104-9