Safety and Performance Study for Venous Large Hole Vascular Closure Device - ELITE study

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The objective of this study is to evaluate the safety and effectiveness of the PerQseal Elite vascular closure system when used to achieve haemostasis of common femoral venotomies created by 14 to 22F sheaths (venotomy up to 26F) in patients...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON56505

Source
ToetsingOnline

Brief title
PerQseal Elite Venous Clinical Study (ELITE-Venous)

Condition

- Vascular therapeutic procedures

Synonym
venotomy, venous puncture

Research involving
Human

Sponsors and support

Primary sponsor: Vivasure Medical Ltd.
Source(s) of monetary or material Support: Vivasure Medical Ltd.

Intervention

Keyword: ELITE, Vascular Bore, Vascular Closure, Venotomy

Outcome measures

Primary outcome

Primary Safety Endpoint: The combined rate of both Major and Minor access site complications attributable to the PerQseal Elite device through 30-days.

The rate of Major access site complications attributable to the PerQseal Elite device§ through 30-days, as adjudicated by the Clinical Events Committee (CEC) as study device related.

The endpoint is a composite comprised of the following elements:

1. Access site-related bleeding due to a failure of the PerQseal Elite device that requires transfusion of blood product(s); OR

2. Device related vascular injury that requires surgical repair; OR

3. Any new and sustained (> 30-days) device-related ipsilateral nerve injury; OR

4. Any new device-related ipsilateral nerve injury requiring surgical repair; OR

5. Device related thromboembolism requiring surgery or endovascular intervention to prevent life-threatening illness or injury; OR

6. Access site infection requiring intravenous antibiotics, drainage and/or extended hospitalisation.

Primary Effectiveness Endpoint: Time to Haemostasis (TTH) defined as elapsed time in minutes from PerQseal Elite (Introducer-sheath and Delivery-device) removal to first observed cessation of common femoral vein (CFV) bleeding (clinically acceptable cessation of venous bleeding), excluding cutaneous or

subcutaneous oozing, and in the absence of a developing haematoma. This is assessed at the end of the index procedure prior leaving the operating room/catheterisation laboratory.

Secondary outcome

Secondary Effectiveness Endpoints:

PerQseal Elite Technical Success Rate: defined as the number of PerQseal Elite devices that are deployed and achieve haemostasis (i.e., cessation of venous bleeding excluding cutaneous or subcutaneous oozing) without need for more than 10 minutes of firm, adjunctive manual compression or alternative treatment (other than adjunctive endovascular ballooning) at target access site, divided by the total number of PerQseal Elite devices where deployment was attempted, within the mITT population. This is a per device endpoint.

PerQseal Elite Treatment Success Rate: defined as the number of subjects who meet PerQseal Elite Technical Success without experiencing a device related Access Site Complication (based on CEC adjudication) through 30-days, divided by the total number of subjects where PerQseal Elite device deployment was attempted, within the mITT population.

Time to Device Deployment (TTDD): defined as the time from insertion of the PerQseal Elite delivery device into the PerQseal Elite Introducer sheath to complete removal of the PerQseal Elite (delivery device and introducer-sheath) from the subject following PerQseal Elite deployment.

Time to Ambulation: defined as: the elapsed time from PerQseal Elite removal from the subject post deployment until the subject can walk 20 feet/6 meters without venous re-bleeding at the target access site. This endpoint will be

evaluated only for subjects who are ambulatory (e.g., not confined to

wheelchair or bed) at the time of enrolment.

Total Closure Time: Total Closure Time is defined as: Time to Haemostasis (TTH)

plus Time to Device Deployment (TTDD)

Study description

Background summary

The rapid development of percutaneous *minimal invasive therapy* in which multiple disciplines are involved including Vascular Surgery, Cardiac Surgery, Interventional Radiology and Interventional Cardiology, has led to the need for instrumentation to minimise the risk of complications associated with closing the access site, post procedure. Examples of currently emerging percutaneous catheter- based procedures include: Aortic Valve Replacement, Mitral Valve Repair, Tricuspid Valve Replacement, Abdominal and Thoracic Aneurysm Repair, Left Ventricular Circulatory Assist and Extracorporeal Membrane Oxygenation. These procedures require larger size access sites up to 26 French (F). These large access sites are typically created via surgical cut- down to the common femoral vein and closed by surgical repair.

In order to provide a less invasive, percutaneous, safe, secure and simple mechanical closure of these large venotomies and shorten the time taken to perform these closures, Vivasure has developed a family of PerQseal closure devices (PerQseal, PerQseal+ and now PerQseal Elite). The PerQseal closure technology are large hole percutaneous vascular closure devices to induce venous haemostasis in patients undergoing endovascular interventional therapeutic procedures created with sheath sizes 12 - 22 F (venotomy up to 26 F).

The PerQseal Elite has a similar delivery device and mode of operation to both PerQseal and PerQseal+ and similar implant to that of the PerQseal+, however, it is designed with several user interface improvements. Significantly, the PerQseal Elite is designed to be delivered over a 0.035* guidewire (compared to the 0.014* guidewire used with the PerQseal and PerQseal+ devices), this facilitates use of the primary procedure guidewire and eliminates the need for a guidewire exchange to use the Elite device. Other improvements are the addition of a sidearm to the PerQseal Elite sheath for flushing, better blood signalling and blood loss control. Material changes were also made to the device handle components to aid functionality and user experiences. There are no changes to the implant material or methods of manufacture to those of the

PerQseal or PerQseal+ devices.
The PerQseal Elite is a natural extension to the PerQseal family of devices, designed to improve the usability and user interface. These improvements were driven by user feedback and not from any safety issues or concerns from use of either the PerQseal or PerQseal+ devices.

Study objective

The objective of this study is to evaluate the safety and effectiveness of the PerQseal Elite vascular closure system when used to achieve haemostasis of common femoral venotomies created by 14 to 22F sheaths (venotomy up to 26F) in patients undergoing percutaneous catheter-based interventional procedures, with sufficient rigor to provide robust scientific evidence for the demonstration of clinical safety and efficacy of the PerQseal Elite closure system to support a CE-mark and a PMA submission. Note for reference purposes it is expected venotomies created with 14 to 22F sheaths will create a venotomy in the range of 16 - 26F (being the outer diameter of these sheaths).

Study design

This study is a prospective, multicentre, single-arm study to investigate the safety and efficacy of the PerQseal Elite in up to 97 patients at up to 12 European investigational sites. The study shall not be blinded prior to, during or post the procedure. Patients undergoing a percutaneous catheter-based venous interventional procedure (e.g., mitral valve repair, leadless pacemaker implantation, circulatory assist or ECMO via large bore femoral vein catheter) requiring a venotomy created by 14 to 22F sheaths (venotomies up to 26F), via the common femoral vein will be screened against the study inclusion/exclusion criteria. If the patient meets study eligibility requirements, they shall be invited to participate, provide informed consent and shall subsequently be assigned a subject ID number.

Closures may be performed by either clinical specialty, namely; Interventionalist (including Cardiac Electrophysiology Consultants) or Cardiothoracic/Vascular Surgeon.

Patients with bilateral percutaneous access in the common femoral veins where both veins meet all eligibility criteria may, at the discretion of the investigator, have both veins closed with the PerQseal Elite Closure Device. If a PerQseal Elite is used on the contralateral femoral vein then this will be treated as an independent closure for efficacy.

All closures will be percutaneous. An optional adjunctive endovascular balloon may be used to control bleeding if required. Endovascular balloon use is not considered an alternative therapy or a complication.

All subjects shall have a 30-minute, 60-minute, pre-discharge (~48 hours), 30-Days ± 7-Days and 180-Days ± 30-Days follow-up assessments.
A Data Safety Monitoring Committee (DSMC) will be appointed, and patient safety will be monitored closely by the DSMC. Safety data will be reported to the DSMC for every patient with a reported complication/adverse event. The DSMC will review the safety data on a continuous basis to determine whether it is safe to continue enrolment.

Intervention

The name of the product being investigated is the PerQseal® Elite Closure Device. PerQseal® Elite Closure Device will be ised in conjunction with the 18F PerQseal® Elite Introducer. The PerQseal Elite is a vascular closure device designed specifically for large hole venotomies. The PerQseal Elite product consists of an absorbable implant, a Delivery system, Introducer and the associated packaging (inclusive of labelling).

The vascular closure device (VCD) consist of an absorbable implant consisting of both intra-arterial and extra-arterial components, namely the Scaffold, Patch, External Fixation and Pin.

The PerQseal Elite is designed to achieve a secure and rapid seal of the puncture site at conclusion of the procedure with implant absorption within 180-days

Study burden and risks

The following potential benefits associated with use of the PerQseal Elite for access site closure may include, but are not limited to, the following:
• Less invasive percutaneous access and sealing of venotomy compared to surgical cut- down and closure,
• Implant is fully bioabsorbed, leaving nothing permanent in the patient,
• Reduced pain and discomfort as compared to manual compression or surgical access and closure,
• Minimisation of secondary interventions to control bleeding,
• Percutaneous closure leads to shorter overall procedure time compared to manual compression or surgical closure,
• Percutaneous mechanical closure may have lower complications rates than manual compression or cut-down and surgical closure,
• Ability to seal the puncture site for subjects treated with anticoagulation therapy, antiplatelet agents, intravenous glycoprotein IIb /IIIa inhibitors, or thrombolytic agents,
• Delivered and deployed at the conclusion of the primary procedure with no pre- procedure steps,
• Guidewire access maintained throughout the device delivery,
• Minimisation of the temporary disruption of vascular blood flow, which occurs

with manual compression or venous clamping during surgical closure.
• Reduced time to haemostasis compared to manual compression or surgical cutdown.
• Reduced time to ambulation and discharge eligibility compared to manual compression.
• Reduced risk of neurovascular structures damage compared to manual compression, (which may result in pressure trauma to nerves and arterial occlusion).

Taking part in this study can have these cons:
• Patient may experience the side effects or adverse effects of medical device as detailed in section E9
• There may be some discomfort from the measurements during the study.
• Taking part in the study will cost extra time.
• Patient has to comply with the study agreements.

In addition to those listed above there may be unforeseeable risks, which are not known at this time
All patients shall have a 30-minute, 60-minute, pre-discharge (~48 hours), 30-Days ± 7-Days and 180-Days ± 30-Days follow-up assessments.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age >= 19 years.
2. Clinically indicated for a percutaneous venous interventional catheter-based procedure, e.g., mitral valve edge to edge repair, left atrial appendage device closure, leadless pacemaker implantation, patent foramen ovale closure or use of a circulatory assist device or extracorporeal oxygenation using a common femoral venotomy created by a 14 to 24F sheath (venotomy up to 26F).
3. Subject is willing and able to provide appropriate study-specific informed consent, follow protocol procedures, and comply with follow-up visit requirements.
4. Females who are not pregnant or lactating and not planning to become pregnant for the duration of the study.

Exclusion criteria

Baseline Exclusion Criteria: If any Baseline or Procedural Exclusion Criteria listed below are met, then closure with PerQseal Elite device is not permitted,
1. Evidence of current systemic bacterial or cutaneous infection, including groin infection,
2. Known bleeding diathesis, unstable INR, definite or potential coagulopathy, platelet count < 100,000/µl or subjects on long term anticoagulants with an INR > 2.2 within 12 hours prior to index procedure or uninterrupted NOAC administration,
3. Significant anaemia (example: haemoglobin < 8 g/dL or haematocrit < 22%), within 24 hours prior to index procedure,
4. Known type II heparin-induced thrombocytopenia,
5. Documented right ventricular dysfunction < 13%,
6. Ipsilateral or contralateral lower extremity amputation,
7. Previous groin surgery within the region of the ipsilateral vessel access,
8. Common femoral vein diameter stenosis > 50% or previous bypass surgery/stent placement in the common femoral vein of target leg,
9. Known existing nerve damage in the target leg,
10. Nephrotic syndrome or renal insufficiency (baseline serum creatinine > 2.5 mg/dl) or albumin level < 3.5 g/dl or symptoms of pitting oedema,
11. Systolic pulmonary artery pressure > 60 mmHg
12. Known allergy to any of the materials used in the PerQseal Elite device

(refer to Investigator*s Brochure),
13. Subject is unsuitable for surgical repair of the target leg access site,
14. Subject has undergone a percutaneous procedure greater than 8F sheath in the target vessel, within the 90-days prior to index procedure,
15. Subject has undergone a percutaneous procedure of 8F sheath or less using an absorbable intravascular closure device for haemostasis, in the target vessel, within the 90-days prior to index procedure,
16. Subject has undergone a percutaneous procedure of 8F sheath or less using a suture mediated closure device or manual/mechanical pressure for haemostasis in the target vessel, within the 30-days prior to index procedure,
17. History of DVT or pulmonary embolism or venous thrombotic event,
18. Splenectomy or suffering psoriasis or paraesthesia of the ipsilateral leg,
19. Further planned endovascular/catheter-based procedure in the target leg in the 30- days following the index procedure,
20. Subject is enrolled in another investigational medical device or drug study,
21. Subject has been previously enrolled in this clinical study,
22. Subject is unable to maintain ipsilateral leg still during the index procedure (restless leg syndrome),
23. Current COVID-19 infection (with or without symptoms), recent positive test for COVID- 19 within two weeks, or recent exposure to a person with COVID-19 infection within two weeks.

Procedural Exclusion Criteria: *
24. Anatomically the common femoral vein is substantially posterior to the femoral artery,
confirmed by Duplex ultrasound,
25. Initial common femoral venous access achieved other than with the use of an ultrasound guided access approach,
26. If the venous access is, or suspected of being, via an artery,
27. Difficult dilation during initial target femoral vein access (e.g., that damages or kinks dilators) while step-dilating up to the large-bore device,
28. During venous puncture, the target femoral vein suspected to have experienced a posterior venous wall needle puncture or underwent > one needle puncture during the primary procedure, with a needle larger than a micropuncture needle (> 21 gauge or > diameter of 0.819 mm). (Note: not an exclusion if micropuncture technique under ultrasound guidance used for femoral vein access),
29. Subject has a tissue tract (i.e., estimated distance from skin entry point to venous anterior surface at venotomy) expected to be greater than 8 cm,
30. Significant blood loss requiring transfusion of blood products during primary procedure or within 30-days prior to index procedure,
31. Activated clotting time (ACT) > 250 seconds immediately prior to sheath removal or if ACT measurements are expected to be > 250 seconds for more than 24 hours after index procedure,
32. Target puncture site is in a vascular graft,
33. Target venotomy greater than 26F,
34. Target femoral vein diameter is less than 7 mm, based on Duplex ultrasound

or angiography,
35. Evidence of venous diameter stenosis > 20% within 15 mm proximal or distal to venotomy site based on Duplex ultrasound or angiography,
36. Target venotomy has been made in the superficial femoral vein, profunda femoris vein (deep femoral vein), great saphenous vein or located less than 15 mm distal (cranial) to the bifurcation of either the profunda femoris or great saphenous vein and common femoral vein,
37. Target venotomy located behind (posterior) or above (cranial) to the inguinal ligament based upon bony landmarks (above femoral head on A-P projection),
38.Subjects with an acute haematoma > 4 cm diameter, arteriovenous fistula, pseudoaneurysm or intraluminal thrombosis at the target access site identified intra- procedurally,
39. Evidence of bleeding around the primary procedure sheath (VARC type 1/BARC type 2 or higher),
40. Intra-procedural (angiographic or Duplex ultrasound) evidence of venous laceration, dissection or stenosis within the femoral vein that would preclude use of the PerQseal Elite device,

*May not be known until after the patient has given informed consent and the procedure has started. In this event, the PerQseal Elite should not be used, and the patient should be considered excluded from the study and intention to treat analysis.

Note: The use of a secondary closure device in the ipsilateral vessel is prohibited during this study. A note to this effect should be entered into the patient*s medical records.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-04-2024

Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	PerQseal® Elite
Registration:	No

Ethics review

Approved WMO Date:	17-01-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-11-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT06007339
CCMO	NL85435.000.23