Clinical Investigation Plan (CIP) for: Safety and Performance Study for Arterial Large Hole Vascular Closure Device - ELITE study

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To assess safety and performance of the PerQseal Elite Closure Device when used with the 18F PerQseal Elite Introducer to percutaneously close femoral artery punctures and to induce arterial haemostasis in patients undergoing endovascular procedures...

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

Summary

ID

NL-OMON56036

Source
ToetsingOnline

Brief title
PerQseal® Elite Clinical Study - ELITE

Condition

- Vascular therapeutic procedures

Synonym
arteriotomy, artery puncture

Research involving
Human

Sponsors and support

Primary sponsor: Vivasure Medical Ltd.

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

Intervention

Keyword: Arteriotomy, ELITE, Vascular Bore, Vascular Closure

Outcome measures

Primary outcome

Primary Safety Endpoint: The primary safety endpoint is the rate of major access site complications attributable to the PerQseal Elite device through 30-days, as adjudicated by an independent Clinical Events Committee (CEC). 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 percutaneous stent-graft placement, or 3. Any new and sustained (longer than 24 hrs) device-related ipsilateral lower extremity ischemia documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram, which causes a threat to the viability of the limb, and/or requires surgical repair or additional percutaneous intervention, or 4. Surgery for device-related nerve injury, or 5. Permanent (lasting to 30-days) device-related nerve injury, or 6. Access site infection requiring intravenous antibiotics, drainage and/or extended hospitalisation. Primary Effectiveness Endpoint: The Primary effectiveness endpoint is the elapsed time in minutes from PerQseal Elite (Introducer-sheath and Delivery Device) removal from the patient to first observed cessation of common femoral artery (CFA) bleeding, excluding cutaneous

or subcutaneous oozing, and in the absence of a developing haematoma.

Secondary outcome

Safety: Incidence of minor vascular access site complications attributable to the PerQseal Elite Closure Device through 30-days from implantation (inclusive), (as per definitions).

Effectiveness: assessed by technical success rate for the PerQseal Elite Closure Device at discharge or within 5 days of implantation, is non-inferior to a Technical Success Performance Goal derived from a recent focused literature review in an equivalent patient population of the technical success rates associated with alternative large hole closure devices.

Other parameters that will be reported are: PerQseal Elite Treatment Success Rate, Time to Device Deployment, Total Closure Time, Time to Ambulation, Incidence of Major Access Site Complications per VARC-3 and Incidence of Minor Access Site Complications per VARC-3.

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 artery and closed by surgical repair.

In order to provide a less invasive, percutaneous, safe, secure and simple mechanical closure of these large arteriotomies 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 arterial haemostasis in patients undergoing endovascular interventional therapeutic procedures created with sheath sizes 12 - 22 F (arteriotomy 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 primaryprocedure 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

To assess safety and performance of the PerQseal Elite Closure Device when used with the 18F PerQseal Elite Introducer to percutaneously close femoral artery punctures and to induce arterial haemostasis in patients undergoing endovascular procedures requiring an arteriotomy created by 14 to 22 F sheaths. Note, for reference purposes, it is expected arteriotomies created with 14 to 22 F sheaths will create an arteriotomy in the range of 16 - 26 F (being the outer diameter of these sheaths).

Study design

This study will be a prospective, multi-centred, non-randomized study to investigate the safety and performance of the PerQseal Elite. The study shall not be blinded prior to, during or post the procedure. All patients undergoing an endovascular procedure requiring an arteriotomy created by 14 to 22 F

sheaths, via the common femoral artery will be screened against the inclusion/exclusion criteria.

Closures may be performed by either clinical specialty, namely; Interventionalist or Vascular Surgeon.

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

All subjects shall have a pre-discharge, 30-Days ± 7-Days and 180-Days ± 30-Days follow-up assessment. All safety data from the study will be assessed by the Data Safety Monitoring Committee on a continuous basis. Details of follow-up assessments are contained in Table 10-1 of the protocol.

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 arteriotemies. 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 arteriotomy compared to surgical cutdown and closure,
• Implant is fully bioabsorbed, leaving nothing permanent in the patient,
• Reduced pain and discomfort as compared to surgical access,
• Minimisation of secondary interventions to control bleeding,
• Percutaneous closure leads to shorter overall procedure time,
• Percutaneous procedure has lower major complications rates than cut-down access/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,
• Guidewire access maintained throughout the device delivery,
• Minimisation of the temporary disruption of arterial blood flow, which occurs with arterial clamping during surgical closure,
• Reduction in scarring compared to surgical cut-down.

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 should have a scheduled follow-up at discharge, 1 month post-procedure and 6 months post-procedure (with a tolerance of +/- 7 days for 1 month follow-up and +/- 30 days for 6 months follow-up).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Age >= 19 years,
2. Clinically indicated for a percutaneous arterial interventional catheter-based procedure, e.g., transcatheter aortic valve replacement/implantation (TAVR/TAVI) or endovascular abdominal aortic aneurysm repair (EVAR), or thoracic endovascular aortic aneurysm repair (TEVAR), or use of a circulatory assist device or extracorporeal oxygenation using a common femoral arteriotomy created by a 14 to 22 F sheath (arteriotomy up to 26 F),
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:
1. Evidence of current systemic bacterial or cutaneous infection, including groin infection,
2. Known bleeding diathesis, definite or potential coagulopathy, platelet count lower than 100,000/µl or subjects on long term anticoagulants with an INR higher than 2 within 12 hours prior to index procedure,
3. Significant anaemia (example: haemoglobin lower than 9 g/dL or haematocrit lower than 27%), within 24 hours prior to index procedure,
4. Known type II heparin-induced thrombocytopenia,
5. Documented left ventricular ejection fraction lower than 20%,
6. Ipsilateral or contralateral lower extremity amputation,
7. Previous groin surgery within the region of the ipsilateral access,
8. Claudication (Rutherford category 3 or greater), documented untreated iliac or common femoral artery diameter stenosis greater than 50% or previous bypass surgery/stent placement in the common femoral artery of target leg,
9. Known existing nerve damage in the target leg,
10.Renal insufficiency (Glomerular Filtration Rate <= 30 ml/min or baseline

serum creatinine higher than 2.5 mg/dl) or on renal replacement therapy,
11. Known allergy to any of the materials used in the PerQseal Elite device (refer to Investigator*s Brochure),
12. Subject is unsuitable for surgical repair of the target leg access site,
13. Subject has undergone a percutaneous procedure greater than 8F sheath in the target leg, within the 90-days prior to index procedure,
14. Subject has undergone a percutaneous procedure of 8F sheath or less using an absorbable intravascular closure device for haemostasis, in the target leg, within the 90-days prior to index procedure,
15. 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 leg, within the 30-days prior to index procedure,
16. Evidence of marked tortuosity of the femoral or external iliac arteries in the target leg, based on pre-primary procedure CT angiography,
17. Evidence of arterial diameter stenosis greater than 20% within 15 mm proximal or distal to arteriotomy site based on pre-primary procedure CT angiography,
18. Evidence of anterior wall calcification of the target common femoral artery (other than small, diffuse deposits which in the opinion of the investigator will not impede the vascular closure procedure) within 15 mm proximal or distal to arteriotomy site based on pre-primary procedure CT angiography,
19. Target femoral artery diameter is less than 7 mm, based on pre-primary procedure CT angiography,
20. Further planned endovascular/catheter-based procedure in the target leg in the 30- days following the index procedure,
21. Subject is enrolled in another investigational medical device or drug study,
22. Subject has been previously enrolled in this clinical study,
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. Initial common femoral arterial access achieved with manual palpation or blind arterial stick access, without use of an image guided approach (ultrasound or angiography),
25. Difficult dilation during initial target femoral artery access (e.g., that damages or kinks dilators) while step-dilating up to the large-bore device,
26. During arterial puncture, the target femoral artery suspected to have experienced a posterior arterial wall needle puncture or underwent more than one needle puncture during the primary procedure, with a needle larger than a micropuncture needle (greater than 21 gauge or greater than 0.819 mm in diameter). (Note: not an exclusion if micropuncture technique under ultrasound guidance used for femoral artery access),
27. Subject has a tissue tract (i.e., estimated distance from skin entry point to arterial anterior surface at arteriotomy) expected to be greater than 8 cm,
28. Significant blood loss requiring transfusion of blood products during

primary procedure or within 30-days prior to index procedure,
29. Activated clotting time (ACT) more than 300 seconds immediately prior to sheath removal or if ACT measurements are expected to be more than 300 seconds for more than 24 hours after index procedure,
30. Target puncture site is in a vascular graft,
31. Target arteriotomy greater than 26F,
32. Target arteriotomy in the profunda femoris or superficial femoral artery or is in common femoral artery, but within 15 mm proximal of the bifurcation of the superficial femoral/ profunda femoris artery, (apex of bifurcation overlying the femoral head),
33. Target arteriotomy located at the level or above the inferior epigastric artery and/or beneath or above the inguinal ligament based on bony/arterial landmarks (above femoral head on A-P projection),
34.Subjects with an acute haematoma larger than 4 cm diameter, arteriovenous fistula, pseudoaneurysm or intraluminal thrombosis at the target access site identified intra- procedurally,
35. Evidence of bleeding around the primary procedure sheath (VARC type 1/BARC type 2 or higher),
36. Intra-procedural angiographic evidence of arterial laceration, dissection or stenosis within the femoral artery that would preclude use of the PerQseal Elite device,
37. Uncontrolled hypertension (systolic blood pressure higher than 180 mmHg or diastolic blood pressure higher than 110 mmHg) at the time of planned vascular closure,
38. Systolic blood pressure lower than 90 mmHg at the time of planned vascular closure.

*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 same leg 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):	07-12-2023
Enrollment:	23
Type:	Actual

Medical products/devices used

Generic name:	PerQseal® Elite
Registration:	No

Ethics review

Approved WMO Date:	03-10-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-03-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-10-2024
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
Other	CIV-23-06-04319
CCMO	NL84689.000.23