Safety and Performance Study of Large Hole Vascular Closure Device - Frontier V study

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

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

Summary

ID

NL-OMON50786

Source
ToetsingOnline

Brief title
Frontier V

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: De sponsor;Vivasure Medical Ltd.

Intervention

Keyword: Arteriotomy, Frontier V study, Vascular Bore, Vascular Closure

Outcome measures

Primary outcome

Incidence of major vascular access site complications related to the PerQseal®+ Closure Device up to 1 month from implantation (inclusive), is non-inferior to the major device related complication rate associated with alternative large hole closure, derived from a recent focused literature review in an equivalent patient population.

Secondary outcome

Safety: Incidence of minor vascular access site complications directly related to the PerQseal®+ Closure Deviceup to 1 month from implantation (inclusive), (as per definitions).Performance: assessed by technical success rate for the PerQseal®+ Closure Device at discharge or within 5 days of implantation, is non-inferior than the technical success rates associated with alternative large hole closure devices, derived from a recent focused literature review in an equivalent patient population.

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. The currently emerging endovascular or transcatheter procedures include: Aortic Valve

Replacement, Mitral Valve Repair and Abdominal and Thoracic Aneurysm Repair.

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 is developing a new large hole percutaneous vascular closure device to induce arterial haemostasis in patients undergoing endovascular interventional therapeutic procedures created with sheath sizes 14 -22 F(arteriotomy up to 26 F).

Study objective

To assess safety and performance of the PerQseal® + Closure Device when used with the L PerQseal®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 with14 to 22 F sheaths will create an arteriotomy in the range of 16 -26 F (being the outer diameter of these sheaths).

*Note: The PerQseal®*L* Introducer is currently CE marked for use with the PerQseal®Closure Device.The PerQseal®closure device is indicated for the percutaneous sealing of a common femoral arteriotomy in patients following interventional therapeutic endovascular procedures (post primary procedures requiring sheaths in the range of 12-20 F).

Study design

This study will be a prospective, multi-centred, non-randomized study to investigate the safety and performance of the PerQseal®+. The study shall not be blinded prior to, during or post the procedure. All patients undergoing an endovascular procedure requiring an arteriotomy createdby 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, both be closed with the PerQseal®+ closure device. If a PerQseal® + is used on the contralateral femoral artery then this will be treated as an independent closure.All subjects shall have a 1- and 3-month follow-up assessment. All safety data from the studywill be assessed by the Data Safety Monitoring Committee on a continuous basis

Intervention

The name of the product being investigated is the PerQseal® + (plus) closure device. The PerQseal®+ closure device will be used in conjunction with CE marked PerQseal® *L* Introducer. The PerQseal® *L* Introducer is currently CE marked for use with the PerQseal® closure device. The PerQseal® +is a percutaneous vascular closure device designed specifically for large hole arteriotomies. The PerQseal®+ 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, and Extra-arterial-locator. The Scaffold and Extra-arterial-locator are also identical to the already CE marked PerQseal product. There has been a change in the size and shape of the Patch component of the PerQseal®+ implant to facilitate closure of arteriotomies up to 26 Fr.

The PerQseal® + implant is designed to achieve a secure and rapid seal of the access site at conclusion of the endovascular procedure, with implant absorption within 180 days.

Study burden and risks

For the patients involved in this study, the potential advantages of the PerQseal® + over surgical access and sutured closure include the following:
• Less invasive percutaneous sealing of arteriotomy compared to surgical cutdown
• Implant is fully absorbed, leaving nothing permanent behind
• Minimal procedural steps required to achieve haemostasis
• Safe and Effective sealing of 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 (minimisation of steps for access in emergency procedures)
• Percutaneous arterial wire access maintained during the PerQseal® + Closure Device delivery
• Minimisation of the temporary disruption of arterial flow, which occurs with arterial clamping during surgical closure
• Implant is fully removable from the patient (whilst it is attached to the delivery system) after the sealing has been confirmed at the tamponade phase with the implant in its in situ position at the arteriotomy, whilst maintaining percutaneous access via the guidewire.

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 and 1 and 3 month post-procedure (with a tolerance of -7/+14 days for 1 month follow-up). Due to COVID-19 restrictions or other reasons subjects may not be able to return for all scheduled visits, therefore follow-up at 1 month & 3 months may be completed over the phone

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

I. Over 18 years of age.
II. Subject is willing and able to provide appropriate study-specific informed consent, follow protocol procedures, and comply with follow-up visit compliance.
III. Clinically indicated for an endovascular procedure using a common femoral arteriotomy created by a 14 - 22 F sheath.

Exclusion criteria

I. Severe acute non-cardiac systemic disease or terminal illness with a life expectancy of less than four months.
II. Evidence of systemic bacterial or cutaneous infection, including groin infection.
III. Known bleeding diathesis (including severe liver disease), definite or potential coagulopathy, platelet count < 100,000/µl or patients on long term anticoagulants with an INR greater than 2 at time of procedure or known type II heparin-induced thrombocytopenia.
IV. Previous groin surgery within the region of the ipsilateral access.
V. Severe; claudication or peripheral vascular disease (e.g. Rutherford category 3 or greater or ABI < 0.5), documented untreated iliac artery diameter stenosis > 50% or previous bypass surgery/stent placement in the common femoral artery of ipsilateral limb.
VI. Known allergy to any of the materials used in the PerQseal ® + or PerQseal® Introducer (refer to Investigator*s Brochure for materials list).
VII. Subject has undergone a percutaneous procedure using a non-absorbable vascular closure device (excluding suture mediated) for haemostasis in the ipsilateral target leg.
VIII. Patients that have undergone a percutaneous procedure in the ipsilateral leg, within the previous 30 days.
IX. Patients that have undergone a percutaneous procedure using an absorbable intravascular closure device for haemostasis, in the ipsilateral leg, within the previous 90 days.
X. Evidence of arterial diameter stenosis > 20% or anterior or circumferential calcification within 20 mm proximal or distal to target arteriotomy site based on pre-procedure CT angiography.
XI. Females who are pregnant or lactating or in fertile period not taking adequate contraceptives. A pregnancy test may be performed.
XII. Patients that have a lower extremity amputation from the ipsilateral or contralateral limb.
XIII. Target puncture site is located in a vascular graft.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2022
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	PerQseal® + closure device
Registration:	No

Ethics review

Approved WMO

Date:	21-10-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NCTnumberwillbeobtainedbeforestudystart
CCMO	NL76181.000.21

Study results

Date completed: 28-08-2023

Actual enrolment: 2

Summary results
Trial is onging in other countries