InSeal VCD

Published: 22-10-2013
Last updated: 24-04-2024

The objectives of this study are to:• To demonstrate the safety of the InSeal VCD implant. • To demonstrate the safety and functionality of the InSeal VCD delivery system in delivering and deploying of the InSeal VCD implant and withdrawal of the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Observational invasive

Summary

ID

NL-OMON38879

Source
ToetsingOnline

Brief title
InSeal

Condition

- Cardiac valve disorders

Synonym
groin closure, Vascular closure device

Research involving
Human

Sponsors and support

Primary sponsor: Inseal Medical
Source(s) of monetary or material Support: Inseal Medical

Intervention

Keyword: TAVI, Vascular closure device

Outcome measures

Primary outcome

The primary endpoint are:

1. Hemostasis within 15 minutes following vessel access site closure and after

ACT falls below 200 seconds

2. Combined rate of closure-device related major adverse events in first month

Secondary outcome

The secondary endpoint is:

1. Demonstration of delivery system functionality

Study description

Background summary

The increasing variety of arterial devices having a large crossing profile requiring the use of a large bore sheath is mandating focus on large bore closure. Such procedures include endovascular abdominal repair, thoracic aortic repairs and transcatheter aortic valve implantation typically involve sheaths and delivery catheters with 18-25Fr profiles.
Today, the only closing technique (labeled in Europe) available for such large sheath size is the Preclose technique using the 10Fr Perclose Prostar XL. In this technique the Prostar sutures are deployed prior to the insertion of the large sheath with the sutures tied at the end of the procedure. This technique is cumbersome, hard to learn, complex to use and has relative high complications and failure rate.
The InSeal VCD device is easy to use, fast, affords immediate reliable hemostasis, and a single device supports a wide range of sheath punctures size, while leaving a minimal amount material behind and will not limit re-access. While each of these features may be found in one commercial device or another, to date there is no single device that meets all the market requirements

Study objective

The objectives of this study are to:
• To demonstrate the safety of the InSeal VCD implant.

• To demonstrate the safety and functionality of the InSeal VCD delivery system in delivering and deploying of the InSeal VCD implant and withdrawal of the delivery system.
• To demonstrate the effectiveness of the InSeal VCD system in achieving closure

Study design

Prospective, non-randomized study.

Study burden and risks

It cannot be excluded that the InSeal VCD system does not work and the artery needs to be closed surgically. In addition, there may be a thrombosis, resulting in a narrowing of the artery.

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. Candidate for large bore catheterization procedure (such as TAVI, aortic endograft repair) using a CE approved 18Fr access sheath.
2. Femoral, axillary or subclavian artery diameter at sheath insertion site is between 6-10mm
3. Subject age is at least 18 years
4. Patient has signed most recent approved version of the Informed Consent
5. Existence of an additional arterial access port is required in instances where an occluding balloon is planned to be used as a safety precaution.

Exclusion criteria

1. Women Of Child Bearing Potential (WOCBP)
2. Legally non-competent patients
3. Patient participating in another clinical study at the time of the InSeal VCD study
4. Sheath insertion point is less than 12mm proximal to a bifurcation having a diameter greater than 2.5mm
5. Side branch of greater than 2.5mm in diameter less than 4cm proximal to the puncture site.
6. Known severe allergy to metal and membrane material
7. Prior target artery closure with a vascular closure device having intravascular component (such as Angio-Seal) 30 days prior to catheterization
8. Subjects with known coagulopathy, preexisting hematoma, arteriovenous fistula, or pseudoaneurysm at the vessel access site prior to artery closure
9. Patients that do not tolerate aspirin and clopidogrel anticoagulation treatment
10. Prior vascular surgery or vascular graft in region of access site
11. Significant calcification, atherosclerotic disease, or stent within 1.5 cm of the puncture site that may interfere with the operation of the experimental device

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2013
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	vascular closure system
Registration:	No

Ethics review

Approved WMO Date:	22-10-2013
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
CCMO	NL45921.078.13