A Prospective, Multi-Center, Randomized, Concurrently- Controlled Clinical Study of the BARD® COVERATM Arteriovenous (AV) Stent Graft in the Treatment of Stenosis in the Venous Outflow of AV Fistula Access Circuits (AVeNEW)

Published: 28-12-2016
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The objective of this study is to assess the safety and effectiveness of the COVERATMObjectives: Vascular Covered Stent for the treatment of stenotic lesions in the upper extremityvenous outflow of the AV access circuit.

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

Summary

ID

NL-OMON47014

Source
ToetsingOnline

Brief title
AVeNEW study

Condition

- Vascular injuries

Synonym
AV Fistula Access Circuits, Stenosis

Research involving

Human

Sponsors and support

Primary sponsor: Bard Peripheral Vascular. Inc
Source(s) of monetary or material Support: Bard Peripheral Vascular Inc.

Intervention

Keyword: Arteriovenous (AV) Stent Graft, AV Fistula Access Circuits, COVERATM, Stenosis in the Venous Outflow

Outcome measures

Primary outcome

Primary Effectiveness Endpoints with Hypothesis Testing

* Target Lesion Primary Patency (TLPP) through 6 months.

Primary Safety Endpoint with Hypothesis Testing

* Safety through 30 days.

Secondary outcome

Key Secondary Endpoint with Hypothesis Testing

* TLPP through 12 months.

* Access Circuit Primary Patency (ACPP) through 6 months.

Secondary Endpoints without Hypothesis Testing

* TLPP through 30 days, 90 days, 18 months, and 24 months.

* ACPP through 30 days, 90 days, 12 months, 18 months, and 24 months.

* Rate of device and procedure related AEs involving the AV access circuit

through 90 days, 6 months, 12 months, 18 months, and 24 months.

* Total Number of AV Access Circuit Reinterventions through 30 days, 90 days, 6

months, 12 months, 18 months, and 24 months.

* Total Number of Target Lesion Reinterventions through 30 days, 90 days, 6

months, 12 months, 18 months, and 24 months.

* Index of Patency Function (IPF) evaluated at 30 days, 90 days, 6 months, 12

months, 18 months, and 24 months.

* Index of Patency Function * Target Lesion (IPF-T) evaluated at 30 days, 90

days,

6 months, 12 months, 18 months, and 24 months.

* Secondary Patency evaluated through 30 days, 90 days, 6 months, 12 months, 18

months, and 24 months.

* Acute Technical Success.

* Acute Procedure Success (Anatomic and Clinical Success).

Study description

Background summary

The safety and effectiveness of stent grafts has recently been proven in randomized clinical trials. The improvement in AV graft and AV fistula functions was demonstrated with the Bard® FLUENCY® PLUS Endovascular Stent Graft, which was placed for the treatment of in-stent stenotic lesions in the venous outflow of the AV access circuit and supported by a 16.7% access circuit primary patency rate (ACPP) at 6 months, compared to only 3.0% with PTA alone ($p<0.001$) and a 65.2% post-intervention lesion patency rate at 6 months compared to only 10.4% with PTA alone ($p<0.001$) (P130029 approved by FDA on June 17, 2014).
Another randomized clinical trial demonstrated the improvement in AV graft function with the Bard® FLAIR® Endovascular Stent Graft over PTA alone. The Bard® FLAIR® Endovascular Stent Graft, which was placed at the site of venous anastomotic lesions in patients with synthetic grafts, supported a 51% patency rate at 6 months, compared to only 23% with PTA alone ($p<0.001$).

Given results from recent multicenter prospective randomized stent graft trials in AV access, there may be basis for broader use of stent grafts to achieve patency that is superior to angioplasty, alone specifically in the upper extremity venous outflow of subjects dialyzing with an AV fistula. The present

study is designed to evaluate this hypothesis.

Study objective

The objective of this study is to assess the safety and effectiveness of the COVERATM
Objectives: Vascular Covered Stent for the treatment of stenotic lesions in the upper extremity
venous outflow of the AV access circuit.

Study design

This is a prospective, multi-center, randomized, concurrently-controlled clinical study designed to assess the safety and effectiveness of the COVERATM Vascular Covered Stent for the treatment of stenotic lesions in the upper extremity venous outflow of the AV access circuit of hemodialysis subjects dialyzing with an AV fistula.
This study will compare the use of the CovERATM Vascular Covered Stent (following percutaneous transluminal angioplasty (PTA)) to PTA alone. This treatment is called the "Index Procedure."
Follow-up for all treated subjects will be performed at hospital discharge, 30 and 90 days, as well as 6, 12, 18, and 24 months post-index procedure.

Intervention

NA

Study burden and risks

NA

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

Clinical Inclusion Criteria
1. Subject must voluntarily sign and date the Informed Consent Form (ICF) prior to collection of study data or performance of study procedures.
2. Subject must be either a male or non-pregnant female > 21 years of age with an expected lifespan sufficient to allow for completion of all study procedures.
3. Subject must be willing to comply with the protocol requirements, including the follow-up procedures, and be contacted by telephone.
4. Subject must have a mature AV fistula located in an arm, and must have undergone at least one successful dialysis session prior to the index procedure.
Angiographic Inclusion Criteria
5. Subject must have angiographic evidence of a stenosis > 50% (by visual estimation) located in the venous outflow of the AV access circuit and present with clinical or hemodynamic evidence of AV fistula dysfunction.
6. The target lesion must be < 9cm in length. Note: multiple stenoses may exist within the target lesion.
7. The reference vessel diameter of the adjacent non-stenotic vein must be between 5.0 and 9.0mm.
Exclusion Criteria

Exclusion criteria

Clinical Exclusion Criteria
1. The subject is dialyzing with an AV graft.
2. The target lesion has had a corresponding thrombosis treated within 7 days prior to the index procedure.

3. The hemodialysis access is located in the lower extremity.
4. The subject has an infected AV fistula or uncontrolled systemic infection.
5. The subject has a known uncontrolled blood coagulation/bleeding disorder.
6. The subject has a known allergy or sensitivity to contrast media which cannot be adequately pre-medicated.
7. The subject has a known hypersensitivity to nickel-titanium (Nitinol).
8. The subject has another medical condition, which, in the opinion of the Investigator, may cause him/her to be non-compliant with the protocol, confound the data interpretation, or is associated with a life expectancy insufficient to allow for the completion of study procedures and follow-up.
9. The subject is currently participating in an investigational drug or another device study that has not completed the study treatment or that clinically interferes with the study endpoints. Note: Studies requiring extended follow-up visits for products that were investigational, but have since become commercially available, are not considered investigational studies.
Angiographic Exclusion Criteria
10. Additional stenotic lesions (> 50%) in the venous outflow that are > 3cm from the edge of the target lesion and are not successfully treated (defined as < 30% residual stenosis) prior to treating the target lesion.
11. A pseudoaneurysm is present within the target lesion.
12. The location of the target lesion would require the COVERATM Vascular Covered Stent be deployed across the elbow joint.
13. The target lesion is located within a stent.
14. The location of the target lesion would require that the COVERATM Vascular Covered Stent be deployed at or across the segment of fistula utilized for dialysis needle puncture (i.e., "cannulation zone").
15. The location of the target lesion would require that the COVERATM Vascular Covered Stent be placed in the central veins (subclavian, brachiocephalic, Superior Vena Cava (SVC)).
16. Full expansion of an appropriately sized angioplasty balloon, in the operator's judgment, cannot be achieved during primary angioplasty at the target lesion prior to randomization.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2017
Enrollment:	56
Type:	Actual

Medical products/devices used

Generic name:	Covera Vascular covered stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-12-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-10-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-02-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCT02649946
CCMO	NL56228.068.16