everlinQ endoAVF EU Study

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Collect data in an observational study on outcomes of endovascular fistula creation using the everlinQ endoAVF System

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

Summary

ID

NL-OMON42913

Source
ToetsingOnline

Brief title
everlinQ endoAVF EU Study

Condition

- Nephropathies
- Vascular therapeutic procedures

Synonym
Chronic Kidney Failure, End Stage Renal Disease (ESRD)

Research involving
Human

Sponsors and support

Primary sponsor: TVA Medical, Inc.
Source(s) of monetary or material Support: TVA Medical;Inc.

Intervention

Keyword: End Stage Renal Disease (ESRD), Endovascular Artheriovenous Fistula (endoAVF), Hemodialysis

Outcome measures

Primary outcome

All subjects that undergo successful endoAVF creation will contribute to the following outcome measures.

Primary Patency:

Time of successful endoAVF creation until any intervention designed to maintain or reestablish patency or loss of endoAVF patency. The time to first intervention will be calculated as the number of days between the date of endoAVF creation and the date of either the first intervention, date of endoAVF abandonment, or date of last follow-up where patency was evaluated, whichever comes first.

Primary Assisted Patency:

Time interval of successful endoAVF creation until first thrombosis (at endoAVF) causes loss of patency (thrombosis free survival). Interventions employed to keep the fistula usable whether open or surgical (including new anastomosis) do not affect this time.

Secondary outcome

Secondary Patency:

Total time from successful endoAVF creation to complete abandonment. All subjects that undergo a successful endoAVF creation and do not have abandonment due to renal transplant receipt will be included in the outcome measurement.

Cumulative Functional Patency:

The time period from first endoAVF cannulation (2 needle) to endoAVF

abandonment.

Procedure Success:

The successful endoAVF creation rate as assessed immediately post-procedure via

fistulogram, duplex ultrasound, or via presence of thrill/bruit. All subjects

that undergo the everlinQ procedure will contribute to this outcome measure.

Study description

Background summary

End Stage Renal Disease (ESRD) currently affects over 2 million people worldwide. It is projected that the worldwide incidence of ESRD will increase dramatically over the next 10 years, due to the increasing incidence of an aging population, diabetes, hypertension, and obesity. Currently, Renal Replacement Therapy for patients with ESRD consists of either hemodialysis or peritoneal dialysis.

Vascular access is a critical component in the care of patients undergoing hemodialysis. The three methods of long term vascular access available to a patient requiring hemodialysis are: an autogenous arteriovenous fistula (AVF), a prosthetic arteriovenous graft (AVG) or a tunneled dialysis catheter. The AVF has been shown to be superior to AVG and superior to catheter access in terms of both mortality and morbidity.

Though there is widespread agreement that the AVF is the preferred method of vascular access, 28 - 60% of AVFs do not successfully mature and are rendered unusable for hemodialysis. To improve on these results, and decrease the invasiveness of the procedure, a new tool and method for creation of an AVF has been developed, called everlinQ endoAVF System. In particular, the goal is to reduce the surgical manipulation of the blood vessels, particularly the veins in the arm, which typically exhibit intimal hyperplasia in surgical AVF. Intimal hyperplasia is believed to be a root cause of failure in surgical AVF and AVG, and this technology and method may help improve the patency and

maturity of AVF in patients with ESRD.

Study objective

Collect data in an observational study on outcomes of endovascular fistula creation using the everlinQ endoAVF System

Study design

This is a prospective, multi-center study to evaluate the everlinQ endoAVF System when used to create an endoAVF for patients who require vascular access for hemodialysis.

The study may have up to 20 active sites participating in order to enroll up to 200 subjects that undergo successful endoAVF creation with the everlinQ endoAVF System. All patients who meet study inclusion criterial and no exclusion criteria will attempt to undergo the everlinQ procedure. Patients who undergo the everlinQ procedure (catheter insertion and delivery of RF energy) will be enrolled in the study. Patients who do not undergo the everlinQ procedure will be treated per physician and hospital guidelines and will not be considered enrolled in the study. Data outlining what kind of treatment the patients did receive will be documented on the Screen Failure Log.

All subjects who undergo successful endoAVF creation using the everlinQ endoAVF System will be followed for up to 12 months post index procedure.

Intervention

Creation of an endovascular arteriovenous fistula (endoAVF) with the everlinQ endoAVF System for patients who require vascular access for hemodialysis.

Study burden and risks

Benefits:
The everlinQ endoAVF System may facilitate a less-invasive and more reproducible AVF procedure while minimizing surgical incisions as compared to conventional surgical AVF creation. This endovascular approach may lower the risk of procedural infections as compared to surgical AVF creation. Due to the less-invasive nature of the procedure with the everlinQ endoAVF System, the endoAVF may exhibit improved maturation and patency characteristics compared to historical maturation and patency data. In addition, patient recovery time may be decreased, and anesthesia may be minimized compared to a conventional surgical AVF procedure.

Risks:
Most of the potential risks and complications associated with the everlinQ

endoAVF System and procedure are similar to the risks expected for Chronic Kidney Disease (CKD) patients undergoing surgically created AVF or AVG procedures. The potential risks related to the everlinQ endoAVF System and procedure include but not limited to:
• Aborted or longer procedure
• Additional procedures (interventions)
• Bleeding, hematoma (a solid swelling of clotted blood within the tissues) or hemorrhage (an escape of blood from a ruptured blood vessel)
• Bruising
• Burns
• Death (mostly due to CKD related complications not the everlinQ endoAVF device or procedure)
• Electrocution
• Failure to mature (AVF can never be used)
• Fever (pyrogenic reaction)
• Embolism (blood clot or device piece)
• Heart problems such as arrhythmias (abnormal beats) that can be caused due to high levels of potassium in the blood (mostly due to CKD and not the TVA device or procedure)
• Increased risk of congestive heart failure (heart fails due to increased flow from AVF)
• Infection (local or in the blood (bacteremia))
• Numbness, tingling and/or coolness in the fistula extremity
• Occlusion/stenosis (AVF clots)
• Problem due to sedation or anesthesia
• Pseudoaneurysm (leaking hole in artery that forms blood clot on outside of it)
• Sepsis (systemic inflammatory reaction)
• Steal or ischemia (not enough blood flow to hand)
• Swelling, irritation or pain
• Thrombosis (AVF completely clotted and cannot be used)
• Toxic or allergic reaction
• Venous hypertension (arm swelling)
• Vessel, nerve or AVF damage or rupture
• Wound problem

In addition, fistula infiltration injury due to needle cannulation of the fistula is also a known risk/event.
There may also be other potential risks related to use of the everlinQ endoAVF System and procedure that are unforeseen at this time.

Minimization of Risk:
To minimize the risks, the everlinQ endoAVF System has undergone pre-clinical testing. In addition, all Investigators participating in this clinical trial will be trained on the everlinQ procedure which will contribute to minimizing risks associated with the use of the device.
Qualified physicians trained on the study protocol will also utilize the established eligibility criteria to select appropriate patients to participate

in the study.

Contacts

Public
TVA Medical, Inc.

Bee Cave Rd., Suite 250 7000
Austin, TX 78746
US
Scientific
TVA Medical, Inc.

Bee Cave Rd., Suite 250 7000
Austin, TX 78746
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Adult (age >18 years old)
2. Established, non-reversible kidney failure requiring hemodialysis (stage 4 or 5 renal disease) including pre-dialysis patients
3. Target treatment vein diameter(s) for fistula creation >= 2.0 mm as measured via Duplex Ultrasound or Venogram
4. Target treatment artery diameter >= 2.0 mm as measured via Duplex Ultrasound of Arteriogram
5. Both radial and ulnar artery flow to the hand

Exclusion criteria

1. Known central venous stenosis or central vein narrowing > 50% based on imaging on the same side as the planned AVF creation
2. Absence of perforator feeding the target cannulation vein(s) via Venogram
3. Occlusion or stenosis >50% of target cannulation cephalic or basilic vein
4. Target cannulation vein that is >6 mm deep
5. Target cannulation vein that is <2.5 mm in diameter
6. Significantly compromised (>=50% stenosis) flow in the treatment arm as determined by physician and imaging
NOTE: patients that have >=50% arterial stenosis my undergo a Digital Brachial Index (DBI) test, if DBI result is <.65 patient is excluded
7. Documented ejection fraction (EF) <=35% in the last 6 months
8. Pregnant women
9. New York Heart Association (NYHA) class III or IV heart failure
10. Hypercoagulable state
11. Known bleeding diathesis
12. Immunosuppression, defined as use of immunosuppressive medications used to treat an active condition
13. Documented history of drug abuse including intravenous drugs within six months of AVF creation
14. *Planned* concomitant major surgical procedure within 6 months of enrollment or previous major surgery within 30 days of enrollment
15. Known allergy to contrast dye which cannot be adequately pre-medicated
16. Known adverse effects to sedation and/or anesthesia which cannot be adequately pre-medicated
17. Evidence of active infections on the day of the index procedure
18. Estimated life expectancy < 1 year
19. Patient is not willing to provide written informed consent, is not geographically stable and/or not willing to comply with required follow-up

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):	22-09-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	everlinQ endoAVF System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-02-2017
Application type:	First submission
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	NCT02682420
CCMO	NL57371.068.16