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Prospective multi-centre observational pilot study to investigate the safety and efficacy of the Venous Window Needle GuideTM (VWNG) (SAVE-2 study)

Submission date
02/04/2014

Recruitment status
Stopped

Registration date
29/07/2014

Overall study status
Stopped

Last Edited
07/06/2017

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Haemodialysis is a treatment that replaces much of the work done by the kidneys. It filters the blood and gets rid of harmful waste, extra salt and water from the body. The treatment is literally a life-saver for patients with advanced kidney failure (where the kidney has stopped, or almost stopped, working). It requires ongoing and safe access to the patients bloodstream so that the blood can be removed, filtered and then returned to the body. An arteriovenous fistula (AV fistula), a blood vessel created by connecting an artery and a vein, is used for this purpose. However, in some cases, inserting a needle to get the blood out can be difficult, particularly if the AV fistula is in a deeper location. The problems this can cause can cancel out the benefits of creating the AV fistula. The main aim of this study is to test the long-term safety and performance of a new device called the Venous Window Needle GuideTM (VWNG) device designed to help with the needling of difficult-to-needle AV fistulae.

Who can participate?
Patients with problematic fistulas or patients wishing to self-cannulate (insert their own needles) and with a life expectancy of at least one year.

What does the study involve?
Participants have surgery to insert the VWNG device. The success of the procedure is assessed and all patients are followed up after a year.

What are the possible benefits and risks of participating?
The potential benefits for each participant is a AV fistula that works better. Risks include possible infection and bleeding.

Where is the study run from?
Central Manchester University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2013 to June 2014

Who is funding the study?
Vital Access Corporation (USA)

Who is the main contact?
Dr Sandip Mitra
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
14213

Study information

Scientific Title
Prospective multi-centre observational pilot study to investigate the safety and efficacy of the Venous Window Needle GuideTM (VWNG) (SAVE-2 study)

Acronym
SAVE-2

Study objectives
The main aim of the study is to evaluate the long-term safety and efficacy of the VWNG device. The VWNG is a CE marked device and is intended to facilitate needling of difficult-to-needle dialysis fistulae.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester South, 16/01/2013, ref: 12/NW/0869

Study design
Non-randomised; Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Renal disorders; Subtopic: Renal disorders; Disease: All Renal disorders

Interventions
The study aims to evaluate the use of the VWNG device when surgically applied to the arterial fistula. The patients will be followed up for 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. The primary safety endpoint is the rate of device or procedure-related serious adverse events
2. Depth and dimension of vessel and how problematic the fistula is, measured at baseline
3. Scan to assess patency and AVF flow at 3 and 12 months

Key secondary outcome(s))
N/A

Completion date
10/06/2014

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. The participant has an un-cannulatable (per the provided definition) upper arm or forearm cephalic, basilic or brachial vein outflow arteriovenous (AV) fistula AND/OR the subjects and their clinicians opt for self-cannulation
2. The participant has received or is in imminent need of receiving haemodialysis treatment and will receive in-center or home haemodialysis treatments at least two times per week
3. Subjects fistula diameter is at least 5 mm at the planned site of device attachment
4. Buttonhole cannulation technique is appropriate for the subject
5. Subjects fistula does not have clinically significant flow abnormalities and has adequate fistula flow (=400 ml/min) to achieve optimum dialysis or dialysis as prescribed
6. The AV fistula is in the range of 4 to 15 mm in depth at the anticipated VWNG access site(s)
7. Subjects life expectancy is at least 1 year, based on clinicians assessment of medical condition

8. The participant has understood the Informed Consent and has agreed to participate in the study
9. Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Subject has recent (within past month) occurrence and/or intervention for AV access stenosis or thrombosis
2. Subject has AV fistula that has undergone a major revision such as AVF resection with PTFE graft insertion, vascular stent placement at cannulation site, complete ligation or closure, requires construction of new anastomosis, a flow-limiting procedure including a DRIL or banding procedure or surgical intervention for an aneurysm at the implant site
3. Subject has skin infection, hypersensitive skin or skin allergies at potential implant sites
4. Subject is pregnant
5. Subject has Body Mass Index > 50
6. Subject has known bleeding disorder based on medical history and clinical observations, e.g., low platelet count
(<50,000), hypercoagulable state, e.g., antithrombin III deficiency; antiphospholipid or anticardiolipin antibodies; Factor V Leiden; circulating Lupus anticoagulant; active heparin-induced thrombocytopenia; Protein C or S deficiency; or history of recurrent deep vein thrombosis not related to AV access.
7. Subject has active malignancy, e.g., condition either being treated or considered untreatable
8. Subject has active systemic infection, e.g., condition either being treated or considered untreatable or positive blood culture
9. Subject has history of significant cardiovascular event/intervention such as angioplasty or stent placement within the previous 3 months, or myocardial infarction within the previous 6 months.
10. Subject has history of significant peripheral vascular disease requiring a major intervention within the previous 3 months
11. Subject has history of significant neurovascular event such as a major intervention within the previous 3 months or stroke within the previous 6 months.
12. Subject has uncontrolled major symptomatic medical problem, e.g., undiagnosed severe pain, metabolic disturbance, fever, etc.
13. There is likelihood of poor compliance to required dialysis protocol, e.g., history of poor attendance to required clinic sessions or non-compliance to medication
14. Subject has mental incapacity; inability to understand treatment instructions
15. Subject is currently participating in another investigational drug or device study that

clinically interferes with the endpoints of this study
16. Subject has known or suspected allergy to titanium

Date of first enrolment
10/06/2013

Date of final enrolment
10/06/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester Royal Infirmary
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Central Manchester University Hospitals NHS Trust (CMFT) (UK)

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Industry

Funder Name
Vital Access Corporation (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No