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	Prospectively registered
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
29/07/2014	Stopped	Results
Last Edited	Condition category	Individual participant data
07/06/2017	Urological and Genital Diseases	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 Tel: 0161 276 6509

Contact information

Type(s)

Scientific

Contact name

Miss Carla Barrett

Contact details

Manchester Royal Infirmary Oxford Road Manchester United Kingdom M13 9WL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

- 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

Secondary outcome measures

N/A

Overall study start date

10/06/2013

Completion date

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 60; UK Sample Size: 60

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 heparininduced 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

England

United Kingdom

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

Sponsor information

Organisation

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

Sponsor details

St Mary's Hospital Manchester Royal Infirmary Oxford Road Manchester England United Kingdom M13 9WL

Sponsor type

Hospital/treatment centre

Website

http://www.cmft.nhs.uk/

ROR

https://ror.org/00he80998

Funder(s)

Funder type

Industry

Funder Name

Vital Access Corporation (USA)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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