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

Submission date	Recruitment status Stopped	Prospectively registered		
02/04/2014		☐ Protocol		
Registration date	Overall study status Stopped	Statistical analysis plan		
29/07/2014		Results		
Last Edited	Condition category Urological and Genital Diseases	Individual participant data		
07/06/2017		<ul><li>Record updated in last year</li></ul>		

# 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

### 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 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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes