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Plain balloon angioplasty vs. Viabhan stent graft as a first treatment for narrowing of the veins after receiving a graft for haemodialysis

Submission date
26/01/2023

Recruitment status
No longer recruiting

Registration date
30/01/2023

Overall study status
Completed

Last Edited
07/01/2026

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
The kidneys perform a vital function in regulating many chemicals and water in the blood. When the kidneys become diseased, these functions may be affected and if severe enough, can lead to a life-threatening build up of chemicals and water in the body. Whilst a kidney transplant is the ideal treatment for this, most patients with kidney failure require a period of dialysis. Dialysis is where blood is removed from the body, cleaned in a dialysis machine, then returned. A good connection to the machine to allow blood removal and return is the key, and this is called vascular access. Given how important this is, vascular access is often called a patient's lifeline. Arteriovenous grafts (AVG) have increasingly been used to provide vascular access for dialysis. The most common problem with AVG is narrowing at the join of the AVG to a vein (venous stenosis). The traditional treatment for venous stenosis is to stretch this narrowed area with a balloon – an angioplasty. Whilst this works well in the short term, the narrowing often comes back and then needs more treatments. A new treatment for venous stenosis has been developed called a stent graft that can be placed at the same time as the angioplasty. The stent graft is a small metal cage, lined by graft material that acts as a support to stop the narrowing from coming back. Several studies have shown that a stent graft can reduce the number of treatments needed but is not clear whether it is better to use them straight away, rather than wait till after venous stenosis recurs after an angioplasty. The aim of this study is to see which is the best first treatment for venous stenosis – an angioplasty or a stent graft.

Who can participate?
Patients aged 18 years and over with venous stenosis after receiving a graft for dialysis

What does the study involve?
Patients who enter the study will get either an angioplasty or a stent graft as the first treatment for venous stenosis. This decision will be made randomly – like tossing a coin. Both the procedures are standard and commonly done in these centres, each of which has very good outcomes. The researchers will see how the patients get on over the following 18 months, and keep a note of any complications, treatments or admissions to the hospital that happen, and every 3 months ask questions about their vascular access and how they are finding it. From all

this information they will be able not only to tell which option works best, but which option patients like best. This information will change how we provide this service not only in this centre, but throughout Europe and the world. It is a very important study.

What are the possible benefits and risks of participating?
Patients will not receive any direct benefit from the study, but we hope the study will help doctors to provide the best treatment in the future. Both treatments in this study are already performed as standard of care. There are no additional risks in taking part in this study over and above those experienced in clinical care.

Where is the study run from?
NHS Greater Glasgow and Clyde (UK) are the lead UK site and we have other hospitals taking part in London, Cardiff, Italy, Spain and Greece

When is the study starting and how long is it expected to run for?
June 2022 to November 2025

Who is funding the study?
Kidney Research UK

Who is the main contact?
Miss Clare Dolan, clare.dolan3@ggc.scot.nhs.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
293491

ClinicalTrials.gov (NCT)
Nil known

Central Portfolio Management System (CPMS)
54767

Study information

Scientific Title
A randomised trial of plain angioplasty vs Viabhan stent graft as first intervention for venous stenosis in arteriovenous grafts

Acronym
PAVia FIRST

Study objectives
This study aims to determine if an immediate stent-graft (Viabahn) would be a better option than angioplasty alone as first treatment of a significant venous stenosis (>50%) in arteriovenous grafts.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/01/2023, West of Scotland REC 3 (West of Scotland Research Ethics Service, Ground Floor Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0212; WoSREC3@ggc.scot.nhs.uk), ref: 22/WS/0176

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intervention for venous stenosis in arteriovenous grafts

Interventions
This is a multi-site, multi-national, prospective randomized open blinded endpoint (PROBE) trial of the first treatment for a significant VS (> 50%) in patients using an AVG for dialysis.

Pre screening:
Patients will be pre-screened by their treating clinician. They will already have had an evAVG implanted and will be in routine follow up for this surgery. As part of their standard of care they will have a physical exam, medical history taken, concomitant medication recorded, demographic information collected and an ultrasound. If they are identified to have significant venous stenosis they will be approached to take part in the study.

Consent:
VASQOL and EQ-5D will be completed to derive a baseline measure. Patients will be randomised to either plain balloon angioplasty or immediate stent graft.

Procedure:
Patients will undergo their randomised procedure and details of the surgery will be recorded (Plain balloon angioplasty or stent graft).

Follow up months 3,6,9,12,15,18:
Patients will undergo ultrasound (US), be asked to complete the VAS-QoL and EQ-5D questionnaires and have their concomitant medication collected.

Unscheduled Visit:
If the patient experiences complications outwith their scheduled follow up they will be invited to clinic as per local guidance. Participants will be asked to complete the VAS-QoL and EQ-5D at unscheduled visits. Follow up visits will reset to 3 months post unscheduled visit.

Patients will be asked to consent to long term follow up via data linkage, this is an optional part of the research.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Time to vascular access abandonment, as measured by the time from procedure to loss of patency of vascular access. This will be measured at 3 monthly intervals (visits 3-8).

Key secondary outcome(s))
1. Cost of patient care in each arm will be analysed by a health economist. Healthcare resource use data will be collected by electronic case report form (eCRF) from the trial and supplemented from external routine sources, including Hospital Episode Statistics (England) and equivalent databases for other UK nations where feasible. This will be classified into intervention-related resource use (e.g. medical consumables and medicines utilised, the time required to perform the procedure, intervention medical team composition including relevant NHS bands, length of stay etc.) and access-related/follow-up resource use (e.g. access-related complications and hospitalisations, re-interventions, creation of alternative access, GP/nurse/Allied Health Professional/outpatient visits, ambulance attendance, A&E attendance, inpatient admissions, critical care stay). Adverse events related to the intervention that result in resource utilisation will also be recorded and included in the analysis. This will be calculated for the duration the patient is in the trial.
2. Quality of life measured by VAS-QoL and EQ-5D at screening and 3 monthly at visits 3-8
3. Patency of treatment measured by the medical opinion of the staff attempting to use the vascular access for dialysis treatment. After this procedure this will be measured 3 monthly at visits 3-8.
4. Time to re-intervention from randomisation. The treating clinician will decide if reintervention is necessary based on clinical opinion. This will be measured from randomisationuntil re-intervention is needed.

Completion date
06/11/2025

Eligibility

Key inclusion criteria
1. Target lesion:
1.1. A significant (>50%) venous stenosis on US or DSA, but confirmed severity prior to intervention using DSA,
1.2. Related to the venous anastomosis (within 8cm),
1.3. That has been determined as requiring intervention,
1.4. Normal outflow vein beyond this with minimum caliber 6mm,
1.5. No previous intervention for venous stenosis or ipsilateral venous stenosis
2. Age ≥18 at the time of informed consent signature.
3. Capable of complying with protocol requirements, including follow-up.
4. An Informed Consent Form signed by the patient.
5. A previously functioning AVG that has had established normal HD parameters (URR/pressures-flows) for a
minimum of 4 weeks.
6. Patient sufficiently fit to withstand maintenance procedures e.g. thrombectomy.
7. No scheduled renal transplant within 60 days.
8. No other outflow tract stenosis, including a normal ipsilateral central venous pathway.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
7

Key exclusion criteria
1. Pregnant female at the time of informed consent signature.
2. AVG implanted less than 4 weeks previously.
3. A plan for conversion to alternative form of renal replacement therapy within 60 days.
4. A history or evidence of severe systemic disease including:
4.1. History of cancer (excludes BCC) with active disease or active anti-tumor (cytotoxic) treatment within the previous
year;
4.2. Suspected or documented hyper-coagulable state, unless willing to take anti-coagulation;

4.3. Recurrent (>1/year) unexplained thrombotic episodes;
5. Known or suspected central vein stenosis / occlusion on the side of AVG.
6. Treatment with any investigational drug within 60 days prior to study entry.
7. Any condition that in the judgment of the investigator would preclude adequate evaluation of the trial end points.
8. Unwilling or unable to have regular surveillance.

Date of first enrolment
28/02/2023

Date of final enrolment
06/11/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Greece

Italy

Study participating centre
Queen Elizabeth University Hospital
Department of Vascular Surgery
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G51 4TF

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
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Study participating centre

St Thomas's Hospital
249 Westminster Bridge Road
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Study participating centre
The Royal London Hospital
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E1 1BB

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
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CF14 4HH

Study participating centre
Insubria University Hospital
Department of Vascular Surgery and Department of Surgical Sciences
Via Ravasi, 2
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Study participating centre
University Hospital of Patras
Department of Surgery
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Greece
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Kidney Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
With relevant permissions anonymised published data will be made available on request on completion of the study.
clare.dolan3@ggc.scot.nhs.uk

IPD sharing plan summary
Available on request

Study outputs

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