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Access Arteriovenous Grafts (AVGs) vs Tunnelled Central Venous Catheters (TCVCs)

Submission date
15/05/2014

Recruitment status
No longer recruiting

Registration date
27/05/2014

Overall study status
Completed

Last Edited
29/10/2018

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients with end-stage kidney failure need dialysis to remove harmful waste (toxins) from the blood. Haemodialysis is the most common, well known, type of dialysis and is chosen by 90% of patients in the West of Scotland. In haemodialysis, the blood is removed from the patients' body though a vein and the toxins removed by a dialysis machine before being returned. Most people need three sessions a week, with each session lasting approximately 3 to 4 hours. In order to allow haemodialysis, there first needs to be access to one of the patients blood vessels (vascular access). This involves creating an arteriovenous fistula (AVF). This is a surgically modified blood vessel created by connecting an artery to a vein and it allows needles to be inserted into the arm for haemodialysis. Unfortunately, a AVF cannot be used immediately after it has been created. It needs to be left to 'mature' for 6-8 weeks before it can be used. Not every patient can wait 6-8 weeks before dialysis begins - possibly because their kidney failure has presented at a late stage or because of delays in performing the procedure. The recent National Kidney Care Vascular Access Report indicates that 30-35% of patients are referred for AVF less than 90 days prior to the date when they need to start dialysis, leaving insufficient time for planning, surgery and maturation. At the moment, only 40% of patients in the UK start haemodialysis via an AVF. The majority of the others start haemodialysis via a tunnelled central venous catheter (TCVC). TCVCs are plastic lines which are inserted into patients' necks to achieve quick vascular access for haemodialysis. This is far from ideal, however, and steps are taken to insure that this procedure is used as little as possible due to the significantly greater risk of infection and 3 fold increase in mortality rate when compared with using an AVF. One potential alternative to TCVCs is 'immediate access' arteriovenous grafts (AVGs). AVGs provide an intermediate option between an AVF and TCVC. It is a tube of prosthetic material which is inserted into the patients' arm/ leg and joined onto their own blood vessels in a operation. Haemodialysis can be performed within 24 hours of the operation and the risks of infections and other complications are much lower than those of TCVCs. Preliminary work has shown that AVGs are acceptable, practicable and cost-effective alternatives to TCVCs in patients requiring urgent vascular access for haemodialysis. We now propose to test this hypothesis in a randomised trial comparing TCVCs to 'immediate access' AVGs.

Who can participate?
Adult patients aged 18 or over with end stage kidney failure who need urgent vascular access for haemodialysis.

What does the study involve?
Patients will be randomly allocated into one of two groups. One group will receive the AVGs and the other TCVC. They will be followed up and monitored for complications for 6 months.

What are the possible benefits and risks of participating?
Patients receiving the AVG are anticipated to be at lower risk of infection. However, it is a surgical procedure which, in itself, does involve some risk (risks associated with anaesthetic, bleeding and steal syndrome).

Where is the study run from?
Department of Renal Surgery, Western Infirmary, Glasgow, UK

When is study starting and how long is it expected to run for?
1st January 2014. Recruitment is anticipated to take ~ 1 year.

Who is funding the study?
W.L. Gore Associates, UK

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13/WS/0087

Study information

Scientific Title
A randomised controlled trial of immediate Access Arteriovenous Grafts (AVGs) vs Tunnelled Central Venous Catheters (TCVCs)

Acronym
AVG vs TCVC

Study objectives
Early cannulation AVGs+/-AVFs will reduce the rate of culture proven bacteraemia and other complications compared to TCVC.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Committee; 16/08/2013; 13/WS/0087

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
End stage renal disease requiring urgent vascular access for haemodialysis

Interventions
Early cannulation arteriovenous graft (AVG) (Acuseal) vs. tunnelled central venous catheter

Intervention Type

Procedure/Surgery

Primary outcome measure
Rate of culture proven bacteraemia at 6 months (per 1,000 dialysis days)

Secondary outcome measures
1. Culture proven bacteremia rates at 1 year and 2 years
2. Primary, secondary and functional patency rates at 3 months, 6 months, 1 and 2 years
3. Stenosis/ thrombosis/ re-intervention rates (including need for urokinase infusions and TCVC replacement)
4. Cost-effectiveness
5. Quality of life
6. Mortality and cardiovascular morbidity at 1 year and 2 years
7. Efficiency and efficacy of dialysis [urea reduction ratio (URR), Kt/V, Qa and recirculation)
8. Delays to treatment and the impact on service provision
9. Readmission rates
10. Other adverse events

Overall study start date
01/01/2014

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. All adult patients 18 years or older with end stage renal disease requiring urgent access to permit haemodialysis.
2. Both patients new to dialysis and those with long-term TCVCs who require new access for haemodialysis will be eligible for inclusion in the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
118

Key exclusion criteria
1. Significant cardiorespiratory co-morbidities
2. Significant systemic sepsis

3. Women who are pregnant or breast feeding
4. Lack of capacity or inability to provide informed consent
5. Declines participation in the study
6. Claustrophobia or severe back pain (MRI end-points only)

Date of first enrolment
01/01/2014

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Western Infirmary
Glasgow
United Kingdom
G116NY

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/05kdz4d87

Funder(s)

Funder type
Industry

Funder Name
W.L.Gore & Associates (UK)

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?
Protocol article	protocol	08/02/2015		Yes	No
Results article	results	07/05/2016		Yes	No
HRA research summary			28/06/2023	No	No