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Is colour duplex ultrasound more sensitive than clinical assessment in predicting early failure of primary arteriovenous fistulae (AVF)?

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Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 09/06/2017	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Matthew Bell

Contact details
Southmead Hospital
Westbury on Trym
Bristol
United Kingdom
BS10 5NB
+44 (0)117 959 6363
matthew.bell@nbt.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0234190027

Study information

Scientific Title
Is colour duplex ultrasound more sensitive than clinical assessment in predicting early failure of primary arteriovenous fistulae (AVF)?

Study objectives
1. Principal question: is ultrasound surveillance of primary AVF necessary or is clinical assessment adequate
for primary AVF survival?
2. Principal objective: to define a method to reduce early primary AVF failure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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
Cardiovascular: Primary arteriovenous fistula

Interventions
Purpose of Study:
This study is intended to improve the service available to patients attending hospital for chronic kidney disease (CKD). Many patients suffering from CKD will require some sort of kidney replacement therapy. Some may be fortunate enough to receive kidney transplant, however those that are not so fortunate will need dialysis of some kind. Dialysis is available in two ways: Peritoneal and Haemodialysis (HD). This study is concentrated on those preparing for HD. In order to begin dialysis a 'man-made' short circuit of the circulatory system must be created. This involves the connection of a vein to the side of an artery in the arm of the patient. This connection allows the development of the vein into a significantly larger vessel that allows easy

needling during dialysis. This also means that the volume of flow through this connection, known as an arteriovenous fistula (AVF), also increases dramatically. It is this high blood flow that allows the patient to receive dialysis in just a few hours, when the flow of blood is reduced the time taken to dialyse is vastly increased. The development of these AVF is not always simple and they can often fail, sometimes only minutes after surgery. In order to improve the chances of survival we would like to investigate the protocols currently used to survey these AVF during development and assess the use of a new protocol and technique. Currently clinical assessment of the developing AVF occurs around two weeks post operation. Any problems identified at this stage mean the patient can be referred for an alternative investigation. This alternative investigation is duplex ultrasound. Evidence supports ultrasounds ability to identify accurately any abnormality in the developing AVF without the need for an invasive technique. This study aims to compare the ability of clinical assessment and ultrasound to accurately predict the outcome of a developing AVF. Whilst doing this we intend to identify the most accurate time for ultrasound surveillance of the developing AVF.

Methodology
Consented patients will be randomly allocated to one of two groups:
Group 1: Clinical assessment
Group 2: Ultrasound assessment

Patients in both groups will be seen in the vascular laboratory for a pre access vein map to be produced. This allows the surgeon to choose the optimum location for the AVF to be created. It will also reduce the chance for bias towards those patients that require pre-access vein mapping as a result of an inconclusive clinical assessment.
Group 1: These patients will be seen by Tessa Savage (renal coordinator) to perform a clinical assessment of the developing AVF on two occasions, firstly 2 weeks post operation and secondly; 6 weeks post operation. Should any abnormality be identified by the clinical assessment then the patient will enter the normal pathway of care.
Group 2: These patients will be seen by Matthew Bell (clinical vascular scientist) to perform a duplex ultrasound surveillance scan. This scan will occur on five occasions: immediately post operation whilst still an inpatient, 1 week post operation (outpatient), 2 weeks post operation (outpatient), 4 weeks post operation (outpatient) and 6 weeks post operation (outpatient). Should patients in either group become concerned about the development of the AVF outside of the appointment times then they will be encouraged to contact either Matthew Bell or Tessa Savage to arrange further examination.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The specificity and sensitivity of both clinical assessment and ultrasound in predicting AVF success or failure
2. ROC curves will be used to identify the most accurate ultrasound criteria found for predicting AVF failure or success
3. ROC curves will also be used for identifying the optimum time for ultrasound surveillance.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2007

Completion date
01/06/2008

Eligibility

Key inclusion criteria
Both groups will be recruited in the same way through the renal consultants and will be randomly allocated to one of two groups. It is predicted that the sample size will be no more than 144 patients in the first year as this is the predicted maximum number of patients requiring primary AVF in this timescale. It is predicted that the final number of patients required for the sample will be approximately 50 per group as a result of a retrospective study performed previously by Robbin et al (2002).

Inclusion criteria:
1. Adult patient requiring primary AVF
2. No previous AVF or dialysis via central line
3. Upper limb vein/artery suitable for AVF formation
4. The patients' eGFRml/min/1.73m^2 must be greater than 15 to minimise likelihood of access being required before maturation of primary AVF

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
144

Key exclusion criteria
1. Children (<18 years old)
2. Those patients unable to give consent
3. AVG formation required
4. Previous AVF
5. Previous access via central line
6. Patients with failing transplant
7. Patients undergoing peritoneal dialysis

Date of first enrolment
01/02/2007

Date of final enrolment
01/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)207 307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
North Bristol NHS Trust

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