

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	☐ Statistical analysis plan ☐ Results
Last Edited 09/06/2017	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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/1.73m² must be greater than 15 to minimise likelihood of access being required before maturation of primary AVF

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Southmead Hospital

Bristol

United Kingdom

BS10 5NB

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

North Bristol NHS Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration