ISRCTN39571402 https://doi.org/10.1186/ISRCTN39571402

Influence of two local anaesthetic techniques on the survival of arteriovenous fistulas created for renal dialysis access

Submission date
27/11/2011

Recruitment status
No longer recruiting

Registration date
18/01/2012

Overall study status
Completed

Last Edited
27/03/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Patients with terminal kidney disease (i.e. non-functioning kidneys) need to attend hospital for dialysis a few times a week, depending on how bad their kidney function is. The dialysis machine is attached to the patient by means of needles inserted in an arteriovenous fistula on the patient 's arm. An arteriovenous fistula provides easy access by means of a needle to a high flow of blood that is taken up the dialysis machine, processed, cleaned and returned back to the patient. These fistulas are created by sewing a vein onto an artery, usually in the forearm or elbow crease just below the skin. Once the fistula is ready it can be used time and time again for dialysis. The fistula operation can be done under general anaesthesia, regional anaesthesia (i.e. numbing the whole arm) or local anaesthesia (i.e. numbing the area where surgery takes place such as elbow crease or wrist). By far, most operations are done under local or regional anaesthesia with patients awake. The decision between local or regional anaesthesia is a matter of patient preference and local guidelines. Both techniques are widely accepted and used across the UK. Currently there is no evidence guiding best practice. Unfortunately for various reasons these fistulas tend to shut down over time. Studies have tried to address this but despite some advances, fistula failure still happens. At one year about 35% of fistulas fail, hence 3-4 out of 10 patients will require another fistula operation. Our study aims to compare the survival of fistulas created under regional anaesthesia versus local anaesthesia. There is recent evidence suggesting that creating these fistulas under regional anaesthesia helps to keep them open for longer. One of the main reasons this is thought to happen is because numbing the whole arm also causes the blood vessels to dilate (i.e. widen). This increases the flow of blood within those blood vessels and prevents clotting of the fistula. Wider blood vessels are also easier to see and handle and can make the operation easier and reduce blood vessel damage. Fistula operations are done with magnifying glasses so an increase in the size of blood vessels is always welcome.

Who can participate?
Patients aged 18 and over, who require the creation of a new arteriovenous fistula for dialysis.

What does the study involve?
Participants are randomly allocated to one of two groups. Group A have their arteriovenous

fistula created by numbing the area where the surgery will take place (i.e. the elbow crease or the wrist). The numbing injection is given by the surgeon before the operation takes place. The numbness lasts 4-6 hours. Group B have their arteriovenous fistula created by numbing the whole arm. The numbing injection is given by an anaesthetist in the upper arm. They use an ultrasound machine to find the nerves of the arm and help them see exactly where to inject the local anaesthetic. The arm remains numb for up to 24 hours. Movement in that arm is also affected during that time. The fistula operation itself is the same in both groups. We are essentially comparing two anaesthetic approaches to fistula surgery. Both are safe, valid and used interchangeably at our hospital and throughout the country. We would like to know whether one is better.

What are the possible benefits and risks of participating?
By performing the fistula surgery after numbing the whole arm we hope to increase the survival of the fistula. Most fistula surgery in the UK is performed using local anaesthetic rather than general anaesthetic. There are very low risks of developing an allergy to the local anaesthetic. Regional anaesthesia of the arm is a very common and safe procedure, it is not experimental. It is a procedure performed on a daily basis at our hospital and throughout the country. The risks of having the fistula created by numbing the whole arm include injury to the nerves of the arm, which is a very rare complication that may happen to 1 patient in 10,000. The fact that an ultrasound machine is used to guide the injection reduces this risk. No such injuries have been recorded at our hospital despite daily practice. The arm will also be numb for up to 24 hours and movement will be affected. Some patients have reduced movement whilst others cannot use their am at all. The arm returns to normal after the local anaesthetic wears off; movement in the arm returns to normal earlier than sensation.

Where is the study run from?
Sunderland Royal Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2012 to January 2014

Who is funding the study?
Sunderland Royal Hospital (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
N/A

Study information

Scientific Title
Influence of local and regional anaesthetic techniques on arteriovenous fistula access survival - a randomized controlled study

Study objectives
There is an increasing amount of evidence that shows arteriovenous fistulas created under a regional block (i.e. axillary brachial plexus block hence anaesthetizing the whole arm) tend to remain patent for longer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East Sunderland

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
Surgical arteriovenous fistula for renal access dialysis

Interventions
We are comparing two well established approaches to the creation of arteriovenous fistulas for renal access dialysis:

1. Arteriovenous fistula created under regional axillary block using levobupivacaine
2. Arteriovenous fistula created under local anaesthetic infiltration using levobupivacaine

Both groups will undergo Doppler assessment of their fistula at 8 weeks post-operatively to assess flow rates. This test is also undertaken by patients not taking part in the trial, hence not trial specific. Follow up for trial purposes is 8 weeks.

Please note this trial is not a Clinical Trial of Investigational Medicinal Products (CTIMP) (Medicines and Healthcare products Regulatory Agency [MHRA] guidance)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Levobupivacaine

Primary outcome measure
Fistula Doppler flow rate measurement at eight weeks post operatively. This measurement is already performed on all arteriovenous fistulas as part of routine arteriovenous fistula management.

Secondary outcome measures
1. A patient satisfaction survey pertaining to patient experience of the local/regional anaesthetic techniques, the surgical procedure and their overall hospital experience will be undertaken
2. A standardized and validated questionnaire using a 5-point Likert scale will be provided to patients following the procedure and we will ask them to complete it before they leave hospital

Overall study start date
01/01/2012

Completion date
01/01/2014

Eligibility

Key inclusion criteria

1. Patients referred for creation of a new radiocephalic or brachiocephalic fistula who consent to take part in the study and agree to have the procedure performed while conscious.
2. Aged 18 - 90
3. Male and female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
220

Key exclusion criteria
1. Patients who require revision surgery.
2. Having had previous arteriovenous fistula surgery is not a contraindication to recruitment provided the new procedure is not revision surgery
3. Patients undergoing the procedure under General Anaesthetic
4. Known allergy to levobupivacaine (extremely rare)

Date of first enrolment
01/01/2012

Date of final enrolment
01/01/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sunderland Royal Hospital
Sunderland
United Kingdom
SR4 7TP

Sponsor information

Organisation
City Hospitals Sunderland NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.chsft.nhs.uk/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sunderland Royal Hospital (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