ISRCTN27841616 https://doi.org/10.1186/ISRCTN27841616

Arteriovenous fistula cannulation in haemodialysis patients

Submission date 29/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/04/2010	**Overall study status** Completed	
Last Edited 22/07/2013	**Condition category** Surgery	

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
4967

Study information

Scientific Title
A randomised interventional treatment study to determine best practise of arteriovenous fistula cannulation in haemodialysis patients

Study objectives
A randomised controlled trial to assess the best practice needling of the arterio-venous (AV) fistula between buttonhole method and rotating needling sites.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire Research Ethics Committee approved on the 19th March 2007 (ref: 07/Q1602/1)

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Renal and Urogenital; Subtopic: Renal and Urogenital (all Subtopics); Disease: Renal

Interventions
Buttonhole method of cannulation using blunt needles versus normal rotating sites practice with sharp needles.

Follow up length: 12 months
Study entry: single Randomisation only

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
The study has been designed to determine the primary and secondary AVF patency rates at 1 year and the complication rate for each cannulation method.

Parameters to be measured:
1. 1 year AVF primary and secondary patency rates
2. AVF complication rate - haematoma formation, aneurysm formation, surgical or radiological interventions (i.e., stenoses), scar tissue, missed needles, skin infiltration, steal syndrome, clotted AVF, infection, bleeding time post needle removal, neurologic disorder, and frequency and duration of hospital admissions
3. Time to cannulation (i.e speed of setting up dialysis) (at each haemodialysis session). The speed with which a dialysis session is commenced is very important to a patient. They are usually on dialysis for at least 4 hours with extra time needed for travelling in from home, waiting to go on the haemodialysis machine, being cannulated for dialysis, coming off dialysis and then travelling home again. This makes it at least a 6 hour session three times a week any minutes saved have an important impact on the patient!
4. Cannulation pain as measured by a validated visual analogue pain score and use of local anaesthetic. The Royal Berkshire Pain Chart was developed in 1992. The development of the pain tool was led by the Pain Forum in collaboration with the Practice Development Team and Dr. John Mackenzie (Pain Consultant) and included an extensive literature search, Delphi

technique and then piloting on surgical, orthopaedic and medical wards within this Trust. The tool took at least two years to develop. The pain tool formed an important part of the pain point prevalence study (Trust-wide study) (1994) and (1995). Cannulation pain will be recorded at each dialysis session and is expected to take less than 1 minute to complete.
5. Economic analysis for each cannulation method
6. Nurse and patient satisfaction with each method
7. Clinical history: a record of medication including erythropoietin dose and ACEI usage, participant age and sex, site of AVF, previous vascular access procedures, date AVF was first needled and history of diabetes mellitus or ischaemic heart disease
8. Clinical parameters (already measured as part of routine clinical practice): adequacy of haemodialysis prescription (Kt/v), intra-dialytic haemodialysis monitoring (blood flow, Litres of blood processed, BP, AVF venous and arterial pressures) and blood parameters: Hb, C-reactive protein, haematocrit and cholesterol.

These parameters will be assessed by:
1. Review of participant's medical notes and medication lists (also recorded on the Renal Unit PROTON computer system)
2. At each dialysis session:
2.1. Cannulation pain score (patient time less than 1 minute)
2.2. Assessment by nurse and record kept:
2.2.1. Missed needle
2.2.2. Skin infiltration
2.2.3. Haematoma formation
2.2.4. Need for local anaesthesia
2.2.5. Time to cannulation
2.2.6. Bleeding time post needle removal
3. Monthly assessment (as per existing unit practice nothing in addition except for monthly AVF photograph):
3.1. Blood tests as per normal Renal Unit practice (no additional blood tests being performed for participants in the trial). Any changes made to a participant's medication or haemodialysis prescription in response to these results would be made as part of our standard practice and guided by existing protocols by any member of the Renal Unit Multidisciplinary team.
3.2. Transonic ultrasound access blood flow monitoring (as per existing unit practice). Referral made for surgical or radiological intervention as per Unit protocol if indicated by results.
3.3. Monthly photograph of AVF (with a ruler measurement) to assess scar tissue and aneurysm formation
4. Record made over the 1 year period:
4.1. Any radiological or surgical intervention for: Significant stenosis or clotted AVF
4.2. Frequency and duration of hospital admissions
4.3. Nurse preference for cannulation type
4.4. Infection: exit site or blood
4.5. Fistula failure - need for tunnelled dialysis catheter for haemodialysis

Key secondary outcome(s))
No secondary outcome measures

Completion date
16/06/2009

Eligibility

Key inclusion criteria
Any male/female participants (no age limits) receiving hamodialysis via AV fistula who are willing to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
Unable or unwilling to give informed consent

Date of first enrolment
22/10/2007

Date of final enrolment
16/06/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
London Road
Reading
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Sponsor information

Organisation
Royal Berkshire and Battle Hospitals NHS Trust (UK)

ROR
https://ror.org/034nvrd87

Funder(s)

Funder type
Industry

Funder Name
Nipro Europe NV - UK Branch (UK)

Results and Publications

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?
Results article	results	01/07/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes