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The incidence of hand ischaemia following different techniques for formation of elbow arteriovenous fistula

Submission date	Recruitment status	[X] Prospectively registered
27/01/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/05/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/11/2017	Urological and Genital Diseases	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised controlled trial comparing incidence of hand ischaemia following creation of either conventional brachiocephalic fistula or proximal ulnar/radial-cephalic fistula

Study objectives
The risk of developing dialysis access-associated steal syndrome is lower in proximal ulnar/radial-cephalic fistula group than in brachiocephalic fistula group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 1 Research Ethics Committee pending approval as of 28/01/2010

Study design
Prospective 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 failure for permanent dialysis

Interventions
The patients recruited for the trial would be randomised to have either conventional branchiocephalic fistula formation or fistula formation using proximal radial or ulnar artery. The patients suitable for elbow AV fistula would be identified in nephrology clinic and then referred to vascular assess clinic where the patients who are suitable for the trial would be consented. The patients recruited would be randomised to have one of the two techniques of fistula formation. They would be put onto the next available list for fistula formation which would be carried out by experienced transplant specialist registrars or senior clinical fellows.

Immediate post-operative outcomes would be recorded. The first follow up would be carried out in vascular assess clinic 2 to 3 weeks after the operation where patients would have digital pressure measurement and would be assessed for presence of symptoms suggesting of fistula-

associated hand ischaemia. Further follow up would be carried out at monthly intervals in the first 3 months and then three-monthly thereafter. Patients who develop hand ischaemia symptoms would be assessed immediately by the vascular assess team at Addenbrooke's Hospital either when the patient self present or via referral by their local dialysis unit. The intended follow-up period is up to 12 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Presence of dialysis access-associated steal syndrome:
1. Digital pressure measurement
2. Symptoms: cold hand, pain, finger sensibility, strength, cramps
3. Signs: capillary refill time, ulcers, gangrenes
4. Requirement for intervention, surgical revision or ligation

Measured at post-operative vascular assess clinic 2 to 3 weeks after the operation or at any timepoint when patients develop ischaemic symptoms up to 12 months follow-up.

Secondary outcome measures
1. Primary (unassisted) patency rate
2. Secondary (assisted) patency rate
3. Complications: haemorrhage, wound infection, stenosis, thrombosis, aneurysm

Assessed at follow up clinic at monthly interval for the first 3 months and then 3-monthly thereafter.

Overall study start date
01/06/2010

Completion date
31/05/2012

Eligibility

Key inclusion criteria
1. Aged 17 to 90 years, either sex
2. Suitable for elbow autogenous arteriovenous (AV) fistula as primary or secondary access for haemodialysis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

35 patients each arm (70 patients in total)

Key exclusion criteria
Patients unable to give consent

Date of first enrolment
01/06/2010

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Research & Development Department
Addenbrooke's Hospital
Cambridge
England
United Kingdom
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Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Addenbrooke's 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