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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

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
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.

### Key secondary outcome(s))
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.

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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
United Kingdom

England

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

# Sponsor information

**Organisation**
Cambridge University Hospitals NHS Foundation Trust (UK)

**ROR**
https://ror.org/04v54gj93

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Addenbrooke's Hospital (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? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |