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Recruitment Data

Randomised Patients

Total: 60
Aberdeen Royal Infirmary 1
Airedale (Yorkshire) 2
Brighton 1
Guy's & St Thomas' (London) 2
Kings College (London) 1
Newcastle 1
Ninewells Hospital (Dundee) 1
Royal Cornwall (Truro) 1
Royal Devon & Exeter 1
Royal Hallamshire (Sheffield) 6
Southend University Hospital 3
Southampton 2
St George's (London) 33
The Royal London 1
Western General (Edinburgh) 3
Yeovil District Hospital 1

60 Randomised Patients!

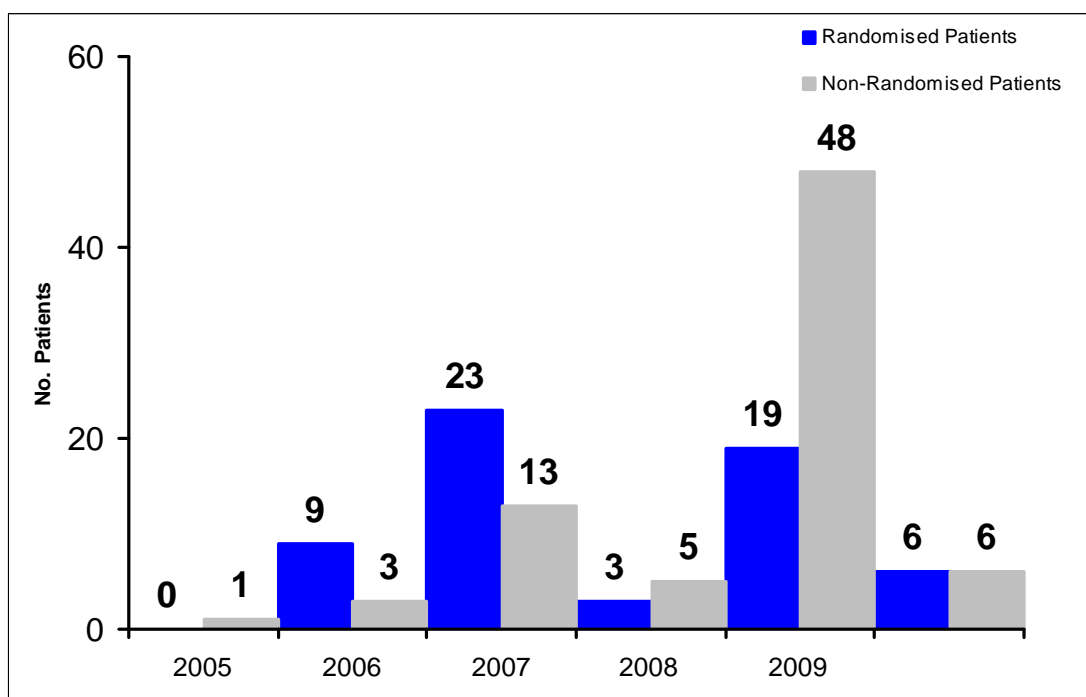
Thanks to those centres continuing to recruit patients to the randomised arm. Two centres have recently recruited 2 – 3 patients into this group. Many thanks extend to:

**Dr Paul Guyler, Christopher Khuoge and team at Southend University Hospital
Dr Sean Slaght and Dr Joanna Lovett at Southampton General Hospital**

We have also seen a number of centres placing their first patients into the randomised arm:

Dr Anand Dixit, John Davies and Ahmed Barkat at Newcastle University Hospitals
Dr Khalid Rashed and Karen Jenkins at Yeovil District Hospital
Dr Ali and Joanna Breeds at Brighton & Sussex University Hospitals

Recruitment Figures (as of 1st March 2010)



New CADISS Co-ordinator

We are pleased to let you know that we have recently appointed Cara Hicks as our new CADISS Co-ordinator. Cara will be joining our team on the 19th of April. Melina Willson will be leaving St George's to return to Sydney on the 5th March. We are very grateful to Melina for all her help and wish her well in her new job at the Cochrane Breast Cancer Review Group. If you have any queries during the period prior to Cara joining the team, Eithne Smith and Rebecca Brookes will be happy to help with urgent enquiries by contacting cadiss@sgul.ac.uk

Participating Centres

Airedale (Yorkshire)
 Aberdeen Royal Infirmary
 Aintree University Hospital
 Brighton & Sussex University Hospitals
 Charing Cross Hospital
 Derriford Hospital (Plymouth)
 Doncaster Royal Infirmary
 Freeman Hospital (Newcastle)
 Guy's & St Thomas' (London)
 John Radcliffe Hospital (Oxford)
 Musgrove Park (Taunton)
 Ninewells Hospital (Dundee)
 Pinderfields General Hospital
 Queen Elizabeth the Queen Mother (Margate)
 Royal Cornwall (Truro)
 Royal Devon & Exeter (Exeter)
 Royal Hallamshire (Sheffield)
 Royal London Hospital
 Royal United Hospital Bath
 Salford Royal Hospitals
 Southend University Hospital
 Southampton General Hospital
 St George's Hospital
 St Mary's Hospital
 The Royal London Hospital
 Torbay Hospital
 University Hospital Leicester
 Watford General Hospital
 William Harvey Hospital
 Worthing & Southlands Hospital
 Yeovil District Hospital

Insight into baseline data

Here is a snapshot of our pre-randomisation data to date. Our randomised and non-randomised group appear to be comparable in most categories. The usefulness of the non-randomised group will be discussed during our next CADISS Trial Steering Committee meeting which will take place on the 27th of April.

Category	Randomised Patients	Non-randomised Patients
Age (mean)	44 ± 12 y (range 18 – 75 y)	45 ± 11 y (range 18 – 73 y)
Gender (male percentage)	40 (67%)	43 (60%)
Site of Dissection	Carotid 36: Vertebral 25	Carotid 39: Vertebral 38
Pre-existing Cardiovascular Risk Factors:		
(i) Treated high blood pressure	10 (17%)	16 (22%)
(ii) Treated diabetes	2 (3%)	4 (6%)
(iii) Treated raised cholesterol	10 (17%)	12 (17%)
(iv) Cholesterol	5.1 mmol/L	5.2 mmol/L
(v) Current smoker	15 (25%)	14 (19%)
Time from onset of dissection or initial TIA/stroke to randomisation	3 ± 2 d (range 0-8 d)	10 ± 8 (range 0-31 d)
Blood pressure at randomisation (based on one measure per participant)	135/82	136/87
Index event (TIA, stroke)	13 TIAs 42 Stroke 4 Horner's syndrome (exclusive) 1 Headache + Neck pain	12 TIAs 46 Stroke 8 Horner's syndrome (exclusive) 2 Headache (exclusive) 1 Neck pain (exclusive) 3 Headache + Neck pain

MREC Approval No. 15

We have recently been granted approval of our Substantial Amendment No.15. This entails:

- 1). **Amended Protocol** which clarifies patient inclusion criteria, SAE/SAR, SUSAR reporting procedures, secondary endpoints and informed consent processes
- 2). **New and amended Informed Consent Forms** so to provide the option of obtaining assent and witnessed consent
- 3). **New and amended Patient/Relative Information Sheets**

We will be sending the approved versions of these documents to all participating centres shortly.

Please ensure that these documents are forwarded to your R&D department and that the Principal Investigator and research team have read and acknowledged receipt of the new protocol.

Also, we would like to receive written confirmation that the CRFs have been updated with new consent forms, patient information sheets and GP letters containing local header paper.