

Co-Chief

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Recruitment Data

Randomised Patients

Total: 87
Aberdeen Royal Infirmary - 1
Aintree Hospital - 4
Airedale (Yorkshire) - 2
Brighton - 1
Charring Cross - 1
Freeman Hospital - 1
Guy's & St Thomas' - 3
King's College - 1
Leicester - 1
Musgrove Park - 1
Ninewells Hospital - 2
QEQM - 1
Royal Cornwall - 1
Royal Devon & Exeter - 3
Royal Hallamshire - 7
Royal London - 1
Southampton 2
Southend - 5
St George's - 38
Watford - 7
Western General (Edinburgh) - 3
Yeovil District Hospital 1

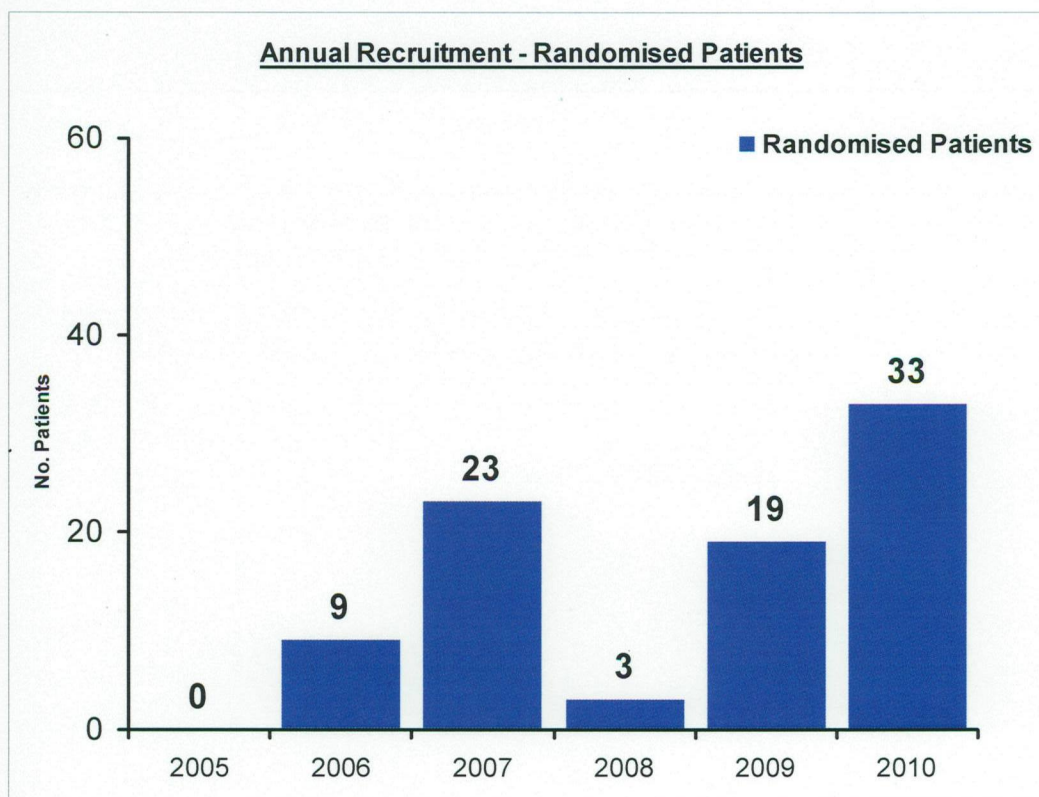
87 Randomised Patients!

Many thanks to those centres who have recruited since the last newsletter. Of note, we have seen a number of centres recruit their first patient, namely Ninewells Hospital in Dundee, Charring Cross Hospital and Pinderfields Hospital.

Since the last newsletter in August we have been joined by Dr. Damien Jenkinson and his team at the Royal Bournemouth Hospital. Best of luck with recruitment!

The CADISS Study is still looking for new centres who are likely to be high recruiters. For more information please contact the CADISS Coordinator, Cara Hicks, or refer to the CADISS website - www.dissection.co.uk.

Recruitment Figures (as of 1st November 2010)



Prize for 100th Patient!

As you can see from the recruitment graph above, 2010 has been the best year for recruitment to the CADISS study so far. As more centres join CADISS and an increasing number of centres recruit their first patients to the study, we are hoping to see an even bigger increase in patient numbers over the coming months. As an incentive, the CADISS Coordinating centre will be awarding a prize to the centre that manages to recruit the 100th patient. The prize will be a luxury Christmas hamper for the whole team to enjoy. This will be a major landmark for the study and we want to show our appreciation to all those centres who are currently recruiting.

CADISS centres open for recruitment:

- 1) Aberdeen Royal Infirmary
- 2) Aintree Hospital
- 3) Airedale
- 4) Brighton & Royal Sussex County Hospital
- 5) Charing Cross Hospital
- 6) Derriford Hospital
- 7) Doncaster Royal Infirmary
- 8) Freeman Hospital
- 9) Frenchay Hospital
- 10) Guy's and St Thomas' Hospital
- 11) Harrogate and District Hospitals
- 12) John Radcliffe
- 13) King's College Hospital
- 14) Musgrove Park Hospital
- 15) Ninewells Hospital
- 16) Pinderfields General Hospital
- 17) Queen Elizabeth the Queen Mother
- 18) Royal Bournemouth Hospital
- 19) Royal Cornwall Hospital
- 20) Royal Devon & Exeter Hospital
- 21) Royal Hallamshire Hospital
- 22) The Royal London Hospital
- 23) The Royal United Hospital - Bath
- 24) Salford Royal Hospitals
- 25) Southampton General Hospital
- 26) Southend Hospital
- 27) St Mary's Hospital, London
- 28) St George's
- 29) The Walton Centre
- 30) Torbay Hospital
- 31) University Hospital of Leicester
- 32) Watford General Hospital
- 33) William Harvey Hospital
- 34) Worthing and Southlands
- 35) Yeovil District Hospital

CADISS – Primary and Secondary Events

An important part of any study is the collection of accurate data in a timely manner. Regarding primary and secondary endpoints, we ask that you notify the CADISS Coordinating centre as soon as you become aware that any randomised patient has had an event. We are currently using Patient Event Form Version 2.0 to collect this information. When providing information on the event, be that a stroke, TIA or an incident of amaurosis fugax, please provide as much clinical information as possible in the synopsis section. If you are able to provide an anonymous copy of the patient's discharge summary, that is often very helpful when assessing the event.

CADISS – Serious Adverse Events

As many of you will be aware, St. George's Trust and St. George's University of London have recently been inspected by the MHRA. One of the major themes of the inspection was pharmacovigilance and the reporting of SAEs. For the purposes of the CADISS Study, please find below an outline of the study specific requirements regarding adverse event reporting:

- Information on Adverse Events (AEs) must be recorded in the patient's medical records. The CADISS Coordinating centre will not collect this information centrally.
- Information on **Serious Adverse Events (SAEs)** must be recorded in the patient's medical records and **reported to the CADISS Coordinating centre as soon as you become aware of the incident and within 24 hours.**
- The current version of the protocol (Version 9.0) contains a list of known side effects to anticoagulants and antiplatelets. As such, these events should be reported as SAEs not Suspected Unexpected Serious Adverse Events (SUSARs.)

How do you know if an SAE is a SUSAR or not?

A SUSAR is the culmination of three assessments:

Expectedness, Relatedness and Seriousness

Expectedness: To assess an SAE for expectedness it is essential that you refer to the Summary of Product Characteristics (SmPC) for the drug you are giving to the patient. Any AE that has not previously been described, and is not located in the SmPC, should be reported as unexpected.

Relatedness: To assess an SAE for relatedness the PI and study team must use clinical judgement as well as referring to the SmPC. An important assessment is the change in the patient from baseline and first drug administration to the time of onset of the SAE in question. The SmPC will also list AEs that have been previously described and are known to be related to the drug in question.

Seriousness: This assessment is based on the PI and study team's judgement.

Finally, a little early but.....MERRY CHRISTMAS!!



Although November is only just coming to an end I wanted to take this opportunity to wish you all a very merry Christmas. I hope you all manage to have a nice, relaxing break and I look forward to speaking to you all in 2011.

