UNIVERSITY OF OXFORD

Asymptomatic Carotid Surgery Trial (ACST-2)

2,345 patients today!

November 2016 Newsletter

Winter has arrived here, those of you in sunnier climates do enjoy it!

So far we have 300 patients in 2016. We aim to randomize 36 patients per month for November and December to achieve our goal for this year. Keep up the good work!

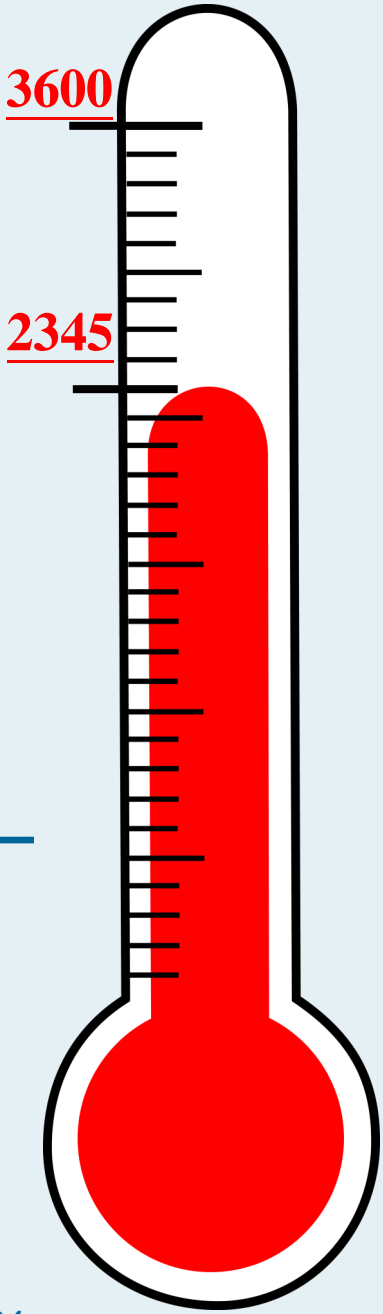
Alison Halliday, Richard Bulbulia, Richard Peto, Leo Bonati & Hongchao Pan

Congratulations to both Serbian Clinical Centre and Novosibirsk for recruiting their 100th patient, achieving Diamond status!

Congratulations also to Santa Maria Hospital for recruiting their 75th patient. They have now achieved Gold status!

RIBBON	BRONZE	SILVER	GOLD	DIAMOND	PLATINUM
0-15 pts	25-49 pts	50-74 pts	75-99 pts	100-199 pts	200+ pts

Target by 2019



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Centre News

Foothills Medical Centre received a RIBBON for randomising 15 patients. Very well done Dr Mitha, Dr Hill and the rest of the team! They are now on their way to achieve bronze recruitment status.

First Recruiters

We would like to congratulate:

Dr Kahles & team at Cantonal Hospital Aarau, Switzerland;

Prof Veroux and Dr Giaquinta at Cefalù Fondazione Istituto G Giglio., Italy;

Prof Bastos Gonçalves & the team at Santa Marta, Hospital,Portugal;

who have randomised their first patients into the trial…The start of a wonderful collaboration!

Other News...

The Royal Preston's new PI - **Mr Anselm Asehosem Egun. Mr Joseph** has also moved to The Royal Preston from North Cumbria.

Many thanks to **Dr Gunnar Plate** for his contribution to ACST-2 on his retirement. We wish him well for the future. **Dr Håkan Pärsson** is PI for Lasarettet Helsingborg.

2016 – Annual Follow–ups
2/3rds already received

It is really important to follow patients long-term. Thanks for your help with this task!

Lynda, Alison C and Wojtek

Recruitment

Top Centres 2016

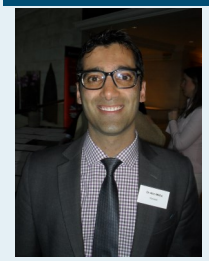
	Novosibirsk Research Institute of Circulation Pathology Russia	37
	Istituto Auxologico Italiano Milan, Italy	21
	Medical University of Innsbruck Austria	15
	Santa Maria Hospital Reggio Emilia, Italy	15
	Serbian Clinical Centre Belgrade, Serbia	15
	University of Bologna Italy	13
	Dedinje Cardiovascular Unit Belgrade, Serbia	12
	University of Basel Switzerland	11
	University of São Paulo Brazil	10
	Teaching Hospital Maribor Slovenia	8
	Malmö Vascular Centre Sweden	7
	Södersjukhuset Stockholm, Sweden	6
	Städtisches Klinikum Karlsruhe Germany	6
	Albert Szent-Györgyi Medical Centre Szeged, Hungary	6
	University of Dresden 'Carl-Gustav-Carus' Germany	6
	Universitäsklinikum Hamburg-Eppendorf Germany	6
	Universitätsklinikum Leipzig Germany	6
	Foothills Medical Centre Calgary, Canada	5
	Klinikum rechts der Isar der Technischen Universität Munich Germany	5
	University Hospital of Larissa Greece	5
	University of Bari Italy	5

The Collaborators' View

Dr Peter Gillgren from Södersjukhuset, Sweden, has been in ACST-2 since 2008 Here are his thoughts.

It has been rewarding and has shed a bright light of knowledge in our research institution at Karolinska Institutet, to be a part of studies such as ACST-1, ICSS and now ACST-2 (!), not to mention our future beneficiaries, our current patients and those yet to come. The Södersjukhuset-team have no recruitment trick other than to always keep scientific studies in mind in our daily routine and never say no to the extra work.

Dr Alim Mitha from Foothills Medical Centre- ACST-2: Canadian View



Given the aging population and the widespread availability of non-invasive diagnostic imaging studies, the detection of asymptomatic carotid artery stenosis is increasing. Despite this apparently increasing prevalence of severe asymptomatic carotid disease, there is ongoing uncertainty in how to manage such patients. ACST-1 demonstrated, in what may be considered a real world scenario, the consequence of immediate endarterectomy for asymptomatic disease versus deferral of any carotid procedure. The results of this study demonstrated that 10-year stroke risks are halved in patients who are immediately treated by endarterectomy.

In Canada, local practice patterns still cause us to treat relatively few asymptomatic patients, with a major reason being the prioritization of symptomatic carotid stenosis patients in a system of fixed resources. There is also an ongoing view that the natural history of asymptomatic carotid disease is comparable to the risk of intervention; in the short-term, this may be true. This view is being challenged, however, given the results of ACST-1, and several trials that directly compare carotid intervention versus current medical therapy are currently recruiting, with results expected in the 2020s. Since we are now encountering more and more patients with asymptomatic carotid disease and the potential for a longer life expectancy; an equally important question to ask, therefore, is between stenting and endarterectomy, if one procedure outperforms the other in this particular population.

Recently, results from CREST-1 and ACT-1 (two North American trials which compared CEA vs CAS in asymptomatic patients) reported results in the New England Journal of Medicine. Both trials suggested CEA and CAS offered similar long-term protection against stroke, but were these analyses were based on relatively few post-procedural strokes and the results were not definite. ACST-2 study will triple the evidence base for this key question, and the results of the study will be arguably more impactful in North America than anywhere else in terms of allocating future resources for patients with asymptomatic stenosis. A head to head comparison of stenting and endarterectomy specifically for asymptomatic disease will demonstrate the true short-term risks and long-term benefits of intervention in this population. Since the benefit of treatment is over the long-term, any advantage of one modality over another, (even if small), will weigh heavily on whether and how asymptomatic carotid disease in this growing patient population will be treated.

The Collaborators' View continued

Dr Estrella Blanco and the team from Universitario de Guadalajara, Spain

The scientific community is still theoretically uncertain how to treat patients with asymptomatic extracranial carotid stenosis. ACST-2 trial is a randomised trial and involves a huge number of patients, so we think it is a good opportunity to investigate what is the best invasive treatment option in patients with asymptomatic carotid artery stenosis. For this reason our Vascular Department decided to participate in this trial. We are located in Guadalajara University Hospital, an academic teaching hospital and we cover all aspects of Vascular Disease. We started our recruitment in 2010, with the collaboration of our neurologist partners. Since then we have recruited 27 patients. We have a screening program for diagnosing carotid stenosis in patients with peripheral arteriopathy disease without stroke or TIA history.

When a patient with high grade internal carotid stenosis is diagnosed, we discuss these cases in a daily conference in our Vascular Department. If both neurologists and vascular surgeons agree on an invasive treatment and patient is eligible for the ACST-2 trial, the patient is invited to enter this trial, after a detailed explanation of the necessity of the treatment and the two different techniques. If patient agrees to participate, randomization is carried out immediately by two physicians.

We perform the two techniques (CAS and CEA) in the Vascular Operating Room. Patients allocated to CAS start dual platelet inhibition therapy two days prior the procedure. In case of CEA, the patients continue with Aspirin treatment. Patients are discharged on day two after the procedure, and control examinations are carried through according to the study protocol. The whole trial process, from consent to randomisation, is quite fluid; the paperwork is straightforward and self-explanatory, not much work! The ACST-2 team have also been very helpful.

Dr Nicola Tusini from Santa Maria Hospital, Italy

Enthusiasm the engine for our participation in this trial, as for the previous trial.

Enthusiasm to participate in a trial organized by a prestigious university such as Oxford University, independent from any economic interests and prestigious is in its scientific reliability

Enthusiasm to participate in that which we believe will be the most important trial for carotid artery stenosis and which will enable us to participate in the creation of the new, future guidelines.

Enthusiasm in creating relationships with national and international colleagues, and meeting them at Collaborators' Meetings in Oxford.

Enthusiasm in seeing the growth of the trial with the positive interim results, despite the perplexity at the beginning from the scientific world towards the trial.

Enthusiasm towards carotid stenting, which seemed definitively to be left behind, but now rather seems to be experiencing a rebirth in its results.

Enthusiasm in including patients in the trial and making them feel part, as we are, in an important scientific project for the prevention of ischemic stroke.

PRIZES - an Approaching Milestone!

When we achieve 2502 randomised patients we will become the largest carotid intervention trial in the world.

To mark this we will send a small celebration Hamper to the team randomising this patient.

There'll also be a second prize - to be decided!

ACST-2 will be at the :

ESO Karolinska stroke update conference—13 - 15th November (Richard Bulbulia)

VEITH— 15th - 19th November (Richard Bulbulia)

UK Stroke Forum — 29th - 30th November (Richard Bulbulia & Alison Halliday)

MAC Munich - 1st - 3rd December (Richard Bulbulia & Alison Halliday)

LINC Leipzig - 24th - 27th January 2017 (Alison Halliday)

A New ACST-2 Team Member!

We are pleased to announce that our new Recruitment Coordinator, Sophie Bradshaw, will be starting in January. In the meantime, please contact Lynda, Alison C, Wojtek or Mary for any questions. acst@nds.ox.ac.uk **or**

+44 (0) 1865 221 345.