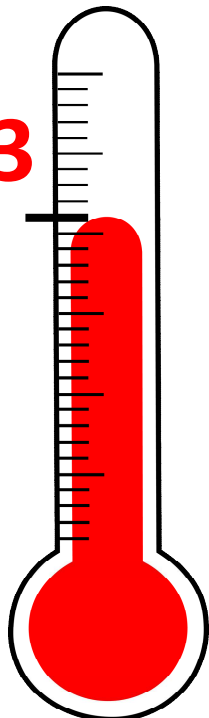




# August 2016 Newsletter

**2273**



*Dear Colleagues,*

*We hope you had a great Summer (Winter, in Brazil!) and now return to work full of energy! The Website shows 2016 recruitment today is at **228** patients – excellent effort everyone!*

*We believe we can recruit **200** more patients in 2016 - by randomising 400 patients each year, we will achieve our goal of 3600 patients by the end of 2019.*

*Our recent very successful German campaign led to 9 patients joining in the summer, fantastic work, well done – 3rd highest recruiting country in 2016 so far! (for more, page 2).*

*As the European Football Championship commenced, ACST-2 also started the Euro Recruitment Challenge, with Italy winning the Cup (more on page 2, again). Well done, to Italy and to every country that participated.*

*With thanks and very best wishes from us all,*

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

The **Data Monitoring (DMC)** and **Trial Steering Committees (TSC)** met recently. Thank you all for helping us prepare for these important meetings. Both TSC and DMC committees were happy with the way that the trial is being run and the quality of the data collected.

The DMC noted the “overall frequency of vascular event within 30 days that (eventually) caused death, or disabling stroke within 30 days’ was reassuringly low around **1%**.”

The TSC was very impressed with the rate of annual follow up forms that were returned in 2015 and hope this will continue!

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### ACST-2 Eligibility Criteria

- No ipsilateral carotid territory symptom for at least 6 months
- Tight Carotid artery stenosis (confirmed by duplex) >60%
- Patient is likely to live for at least 5 yrs
- MRA/CTA shows that CEA and CAS are both suitable
- Patient can have symptoms on the contralateral side

**Our new pocket cards  
Ask us for them!**

# Recruitment

## Country Recruitment for August 2016

	Italy	59
	Russia	28
	Germany	23
	Serbia	19
	UK	16
	Austria	15
	Switzerland	10
	Sweden	11
	Brazil	9
	Greece	7
	Slovenia	7
	Hungary	6
	Canada	4
	Bulgaria	3
	Czech Republic	3
	Japan	2
	Spain	2
	Belgium	1
	Croatia	1
	Israel	1
	Poland	1

## The ACST-2 Euro Recruitment Challenge



Thank you to all who got involved in this country vs country challenge. Italy won the overall challenge – so a big congratulations to those Italian centres – **Istituto Auxologico Italiano, A.C.O. San Filippo Neri, St. Anna University Hospital Ferrara, Mirano Hospital & Santa Maria Hospital** who contributed to the Italian win.

The golden boots for the highest recruiting centre during the ACST-2 Euro challenge went to **Medical University of Innsbruck** and **Novosibirsk Research Institute of Circulation Pathology**, recruiting **5 patients each** so well done to both centres.

## New Centres

**Congratulations** to **Democritus University Hospital Thrace, Greece**, Prof Miltos Lazarides & **St Anna Ferrara, Italy** Prof Francesco Mascoli & Dr Elpiniki Tsolaki who have randomised their first patient into ACST-2!

Also a **warm welcome** to our other centres who have joined ACST-2:

**Hospital de Santa Marta, Portugal** — Prof Frederico Bastos Gonçalves

**Khoo Teck Puat Hospital, Singapore** — Dr Suresh Babu

**Cefalù Fondazione Istituto G. Giglio, Italy**— Prof Pierfrancesco Veroux & Dr Alessia Giaquinta

**Villa Scassi Hospital, Italy**— Prof Gianantonio Simoni

**Cantonal Hospital Aarau, Switzerland**— Dr Timo Kahles

## German Campaign

The goal of the German campaign was for German centres, as a collaborative group, to randomise 10 patients in ACST-2 this summer. **Germany recruited 9 patients** and 4 more already in August! This is the best recruitment period that Germany have had for some time. Well done!!!

**Join a country campaign soon!**

# From you - the collaborators' view from Innsbruck

Continuing our theme from tales from the collaborators we are grateful to  
*Prof Gustav Fraedrich and Dr Barbara Rantner for sharing their thoughts ♦ ♦ ♦ ♦ ♦*



We believe randomised trials are necessary to find out the best way of treating asymptomatic carotid stenosis. This is even more important since CAS is increasingly performed despite lack of evidence for this patient group. Studies comparing invasive versus conservative therapy have been carried through some time ago (ACST-1), had to be stopped (SPACE-2) or have been recently started (CREST-2 and ECST-2).

We started our recruitment for the ACST-2 trial rather late because we were participating in the SPACE-2 trial that was stopped due to low recruitment rates by May 2015. After convincing our neurologic partners to perform an interventional trial with no conservative arm and after completion of all formalities we started in November 2015. Since then we recruited 17 patients. The section of neurovascular diagnostic at our Department of Neurology monitors numerous patients annually. Patients with a symptomatic carotid stenosis are treated urgently within two days. Patients with asymptomatic carotid stenosis that fulfil our criteria for interventional treatment (progression of the stenosis, contralateral occlusion, soft plaque) are discussed in a weekly conference. We routinely perform cerebral imaging in all asymptomatic patients in order to detect silent infarctions or other pathologies. If we (neurologists, vascular surgeons and neuroradiologists) agree on an invasive treatment and the patient is eligible for the ACST-2 trial, the patient is invited to our outpatient clinic. After a detailed briefing on the necessity of treatment and the two

different treatment techniques the patient gets the free choice to participate in the study or not. If the patient agrees to participate, randomization is carried out immediately by two physicians.



Not only the patient selection but also randomization and inclusion into the study is fairly simple. The electronic system is uncomplicated and user-friendly. The support by the ACST team is highly professional and the system of feedback messages is helpful and recommendable.

The allocated therapy will be offered within three weeks. In cases of CAS a dual platelet inhibition therapy will be started at five days prior to the procedure. Patients allocated to CEA are asked to not interrupt the Aspirin or Clopidogrel treatment (in cases where a dual therapy is indicated for other reasons, CEA will yet be performed).

Patients are normally dismissed on day two after CAS and on day three after CEA. Control examinations are carried through according to the study protocol.

We are convinced that the study design and the meanwhile huge number of patients recruited in ACST-2 will help us to answer questions about the best invasive treatment option in patients with asymptomatic carotid artery stenosis. Though there is in our opinion one bias that will be stressed once the study is completed: the "pre-selection" of patients not suitable for CAS because of morphological criteria (calcification, difficult access, etc).

***We are planning another interim paper for ACST-2 – the first 2000 patients! Tables and Figures are being prepared and a draft will be circulated as soon as possible. Your responses will be very important!***

# ACST-2 MRI Sub Study update

This study is led by Dr Leo Bonati and funded by the Swiss Heart Foundation. The aim of the MRI sub-study is to compare the procedural risk of symptomatic and silent cerebral ischaemia between the two procedures and identify risk factors thereof. For this purpose, patients randomized in ACST-2 undergo brain MRI 1-7 days before intervention and 1-3 days after the allocated treatment (surgery or stenting)."

Currently there are 86 patients from University Hospital Basel (n=36), University Hospital of Larissa (n=14), Serbian Clinical Centre Belgrade (n=11), UMC Utrecht (n=9), Istituto Auxologico Milano (n=11) Klinikum rechts der Isar, Munich (n=4) & La Sapienza Rome (n=2). Cantonal Hospital Aarau have also just been initiated.

Centres are remunerated with 400€ per patient if both pre- and post-treatment brain MRI is performed and the clinical data is entered in the electronic CRF. If you are interested in participating please contact Dr Bonati (Leo.Bonati@usb.ch)

## News from the ACST-2 Office



### 2016 – Annual Follow-ups

We have already had a really good response to our annual follow-up letters. We sent out just over **1850** forms and **50%** responded within the first two months - an excellent result! We are particularly delighted to have received forms from 3 centres where follow up was previously very difficult.

We will be sending our 1<sup>st</sup> reminder letters to patients and collaborators in the first week of September. Thank you!

*Wojtek, Lynda and Alison C*

### Staff update

Luisa Teixeira is leaving - we wish her well and thank her for all her hard work, supporting and improving recruitment over the last 2 years. A new Recruitment Co-ordinator will be appointed, but in the meantime, please contact Lynda, Alison C, Mary or Wojtek for any recruitment questions  
[acst@nds.ox.ac.uk](mailto:acst@nds.ox.ac.uk) or +44 (0) 1865 221 345.

Congratulations to Dr Hongchao Pan who has worked with us on ACST trials for over 10 years. Hongchao is now a Co-PI on ACST-2. His expertise in statistical analysis is well-known and he works with Richard Peto on our data, as well as on the recent IPD analysis of all 3 asymptomatic trials (ACST-1, VA and ACAS).

## Upcoming meetings

Siena; 5-7<sup>th</sup> Sept

**Siena Vascular Endovascular Conference ([SIVEC](#))**

Copenhagen;  
28-30<sup>th</sup> Sept

**European Society for Vascular Surgery ([ESVS](#))**

**Thurs 29th Sept: 8:00-9:00am, Carstensen, Djurre de Waard (PhD student), BP in ACST-1  
9:00-10:45am, Carotid Session /Carstensen, Alison Halliday, IPD Analysis  
11:15-12:30, Ongoing Trials/Congress Hall, Alison Halliday/ Richard Bulbulia, ACST-2**

Warsaw;  
19-22nd Oct

**Xth Central European Vascular Forum Congress ([CEVF](#))**

Rome;  
23-25th Oct

**Italian Society of Vascular and Endovascular Surgery ([SICVE](#))**

**SPECIAL ACST-2 SESSION \*\* Sala A, Sunday 23rd Oct, 11:00 -12:30am**

**\*\*Thanks to Prof Nicola Mangialardi, don't miss it!!**