



July Newsletter 2014

THANK YOU for your hard work in recruiting for ACST-2—we have now recruited over **1,500** patients!

- ◇ A total of **173 patients** have been enrolled so far this year
- ◇ March was a record breaking month (our best month ever!) with an amazing **43 patients** recruited
- ◇ **10** new centers have joined ACST-2

This is a really fantastic achievement, thank you all. Please do not stop recruiting new patients, we are nearly half way to reaching our recruitment goal of 3,600. **Keep going; each and every patient counts!**

With best wishes,

The ACST-2 Team

ACST-2

recruitment
to date:

1,503

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Congratulations to the team at **Umberto ASO Mauriziano** in Italy for randomising the **1500th** patient for the ACST-2 trial!

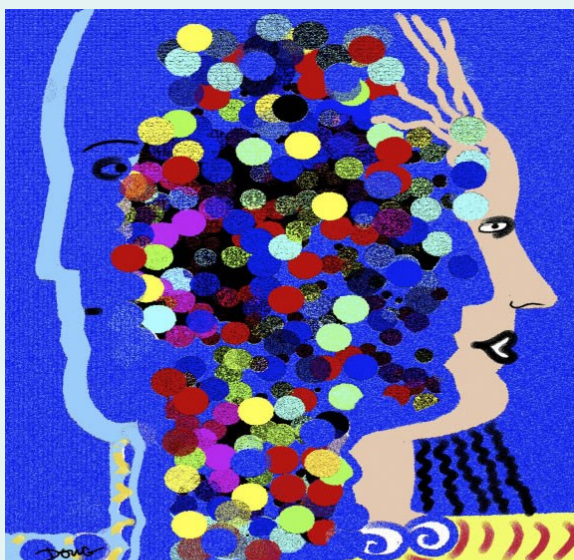
This centre continues to be one of our top performers and has recruited a total of **47 patients** to date in the trial—thank you and **well done!**

2014 European Stroke Conference, Nice



*Trials working
together —*

ACST-2 and ECST-2



23. European Stroke Conference
6 - 9 May 2014
Nice, France

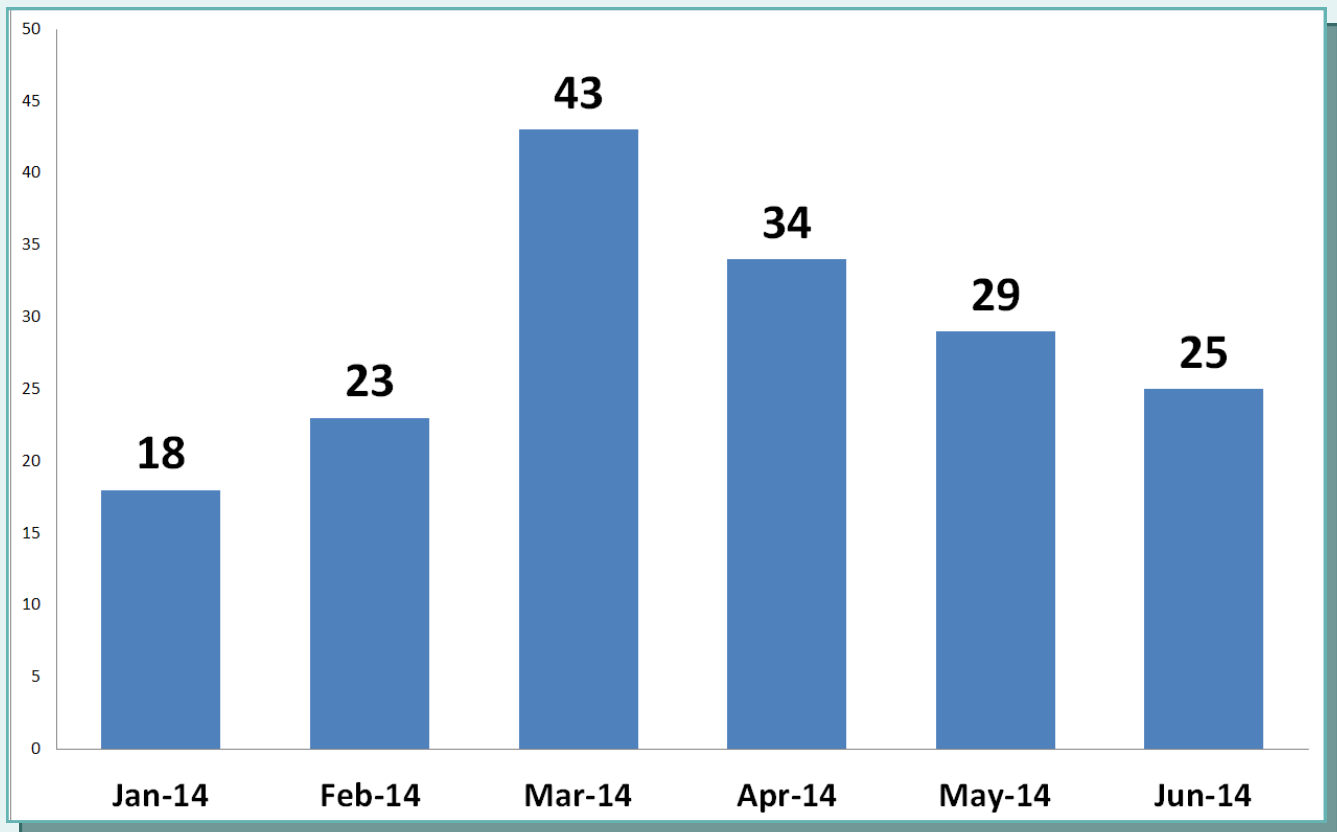


4 NEW centers: Welcome to ACST-2!

- **San Giacomo Hospital, Italy** (led by Dr Cernetti)
- **3rd Surgical Department , Attikon University Hospital, Greece** (Professor Vasdekis) - *has recruited their first patient for ACST-2!*
- **Great Western Hospital, United Kingdom** (led by Dr Ramadurai)
- **Klinikum rechts der Isar der Technischen Universität Muenchen, Germany** (led by Professor Eckstein)

Patient Recruitment Updates...

2014: average number of patients recruited per month: 28.67



Very well done and please keep going!"

Who has recruited patients so far this year?

1,503

Dedinje Cardiovascular Unit	20	Sheffield Vascular Institute	2
Istituto Auxologico Italiano	13	St Anne's University Hospital Brno	2
Poznan University of Medical Sciences	13	Bishop Auckland Hospital	1
NOCSAE Modena	13	Derriford Hospital	1
Novosibirsk R.I. of Circulation Pathology	13	Foothills Medical Centre	1
University Hospital of Larissa	9	Freeman Hospital	1
East Tallinn Central Hospital	7	Guadalajara Hospital	1
Nottingham University Hospital	7	Luton & Dunstable Hospital	1
Santa Maria Hospital	6	MCL Leeuwarden	1
Albert Szent-Györgyi Medical Centre	5	Medical University Hospital of Warsaw	1
University Hospital of Antwerp	5	Peking Union Medical College Hospital	1
Ceske Budejovice - Budweiss	5	Rambam medical Centre	1
Sodersjukhuset	4	Regional Hospital Liberec	1
Serbian Clinical Centre	4	Rijnstate Hospital	1
Umberto I- ASO Mauriziano	4	San Camillo Forlanini	1
Kent and Canterbury Hospital	3	Sendai Medical Centre	1
Semmelweis Medical University	3	Southend University Hospital	1
Vascular Endovascular Unit of Perugia	3	Städtisches Klinikum Karlsruhe	1
Circolo University Hospital	3	Sunderland Royal Hospital	1
Department of Vascular Surgery, Attikon	2	Universitätsklinikum Hamburg-Eppendorf	1
IRCCS Policlinico San Donato	2	University of Basel	1
Lasarettet Helsingborg	2	Wythenshawe Hospital	1
Regional Specialist Hospital, Wroclaw	2	Vascular Unit—3rd Surgical Dept., Attikon	1

A big congratulations to the ACST-2 team at **Dedinje Cardiovascular Unit (Serbia)** for the fabulous efforts they made in recruitment so far: **20 patients** randomized for 2014!

And, since becoming active in February 2014, **Novosibirsk Research Institute of Circulation Pathology (Russia)** has already randomized **13 patients!**

2014 Annual Follow Up Forms

Dear ACST-2 Collaborators,

The year of 2013 had an excellent **96%** rate of Annual Follow-up Forms returned and we are very grateful to all of you who helped us achieve this result!

Here in the ACST-2 office, our aim is to work towards an even higher percentage for the year of 2014.

Thank you very much!

Kind regards,

Lynda and Catilina

2014 has arrived for the ACST-2 Annual Follow-up Forms. On the 12th of June, these forms were sent for the patients up to the **ID 10-13-78**. Some forms were sent to collaborators - thank you in advance for completing the forms on behalf of your patients.

The image shows the top portion of a questionnaire form. The header is in Italian: "Studio internazionale sulle procedure di prevenzione dell'ictus (Questionario annuale; completare ENTRAMBE le pagine)". Below this, there are several input fields: "Data della scheda" (a date picker), "Nome del paziente (IN STAMPATELLO)", "Indirizzo (IN STAMPATELLO), se diverso da quello nella lettera", and "Numero identificativo del paziente" (with a small box for "Indirizzo telefono & e-mail, se conosciuto"). There are also checkboxes for "Indichi [x] chi ha completato questo modulo" with options: "Paziente", "Assistente", "Amico/parente", and "Altro". A black box contains a message in Italian: "Noi speriamo sia stato bene da quando ha lasciato l'ospedale dopo l'intervento all'arteria del collo (CEA/CAS) avuto quando ha preso parte allo studio, ma se così non fosse La preghiamo di dircelo." Below this is a question: "1. Dall'ultima volta che è stato contattato [] S [] N [] C [] , ha avuto un ictus?"

Queries

We also thank you for all your help with the queries on the 2013 forms, and we count with your help again in 2014.

Missing Consent Forms

Please return all your missing initial forms, however it is now **extremely urgent that you return the consent forms** for your patients by the **end of June**. Without a consent form we are not allowed to send the 2014 Annual Follow-up forms. In addition, we also require the **patients' addresses** that were not completed on the consent form. This will impact on the time we will have to collect the information for your patients.

Major Events

Thank you to everyone for returning information for major events. This has made a huge impact when reporting to the Data Monitoring Committee, providing analysis for **myocardial infarctions, strokes and death** within 30 days and **deaths and strokes** post 30 days. We cannot achieve our results without your contribution, please continue to provide all information requested in a timely manner.

When preparing to complete the 2014 Annual Follow-up Forms...

- The forms can be completed in clinic or over the phone with the patient, relative or GP;
- We now require the statin's dosage, please provide this information to avoid queries;
- If you still have queries to be answered for the 2013 forms regarding statin's dosage, at the moment of completing the 2014 forms, please ask your patients for the information missing;
- If you are too busy to complete the Annual Follow-up forms, please remember that these forms can be completed by any admin staff member in your Hospital, even if this person is not involved in ACST-2 yet. In the case that you do not have time to train this person on how to complete the form, please give our email addresses contact (Lynda.tully@nds.ox.ac.uk or Catilina.nobre@nds.ox.ac.uk) and we will arrange a meeting over the phone to provide full training.

Will ACST-2 change the game? (extract from LINC review 2014)

•Will ACST-2 change the game?

•For Carlo Setacci (Siena, Italy), who also spoke during the session, the debate of CAE versus CAS may be silenced thanks to results from the second Asymptomatic Carotid Surgery Trial (ACST-2) – a world-wide stroke prevention study comparing CEA and CAS in patients with asymptomatic carotid stenosis in whom there is substantial uncertainty as to which treatment is more appropriate.²

- The trial has been tasked with comparing the two procedures in stroke prevention with long term follow up of patient from over 26 countries for at least five years. "I have been a keen supporter of carotid artery stenting since the early 2000s," Professor Setacci told *LINC Review*. "In my centre I started a carotid artery stenting programme in 2001, and up to now we have treated almost 3000 patients by carotid stenting. So I am a clear supporter of stenting, and I am really happy about the new interim results by ACST-2."
- "This trial is the largest trial ever conducted to compare stenting

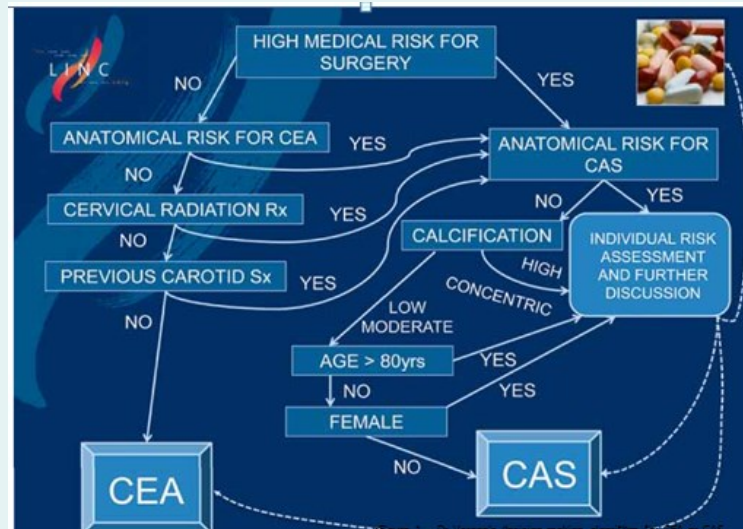
and endarterectomy in asymptomatic patients. One of the major points we know is that we cannot enrol patients when we don't know exactly which procedure is better, so when we are uncertain about what to do we can enrol patients in this trial."

- Early, blinded results from the trial have shown "outstanding" outcomes, Professor Setacci under-lined, with as low as 1% complication rates/death. "We know that this data is even better than data from ACST-1, for carotid endarterectomy: it was 1.7% at that time for stroke and death," he said.

- Referring to the notion of a game-changing shift in the use of carotid stenting in routine treatment, Professor Setacci stressed that ACST-2 has highlighted the importance of better skill sets and operator volumes in improving outcomes. "We published a consensus in Italy in 2006 suggesting that to be considered 'skilled operators' for carotid stenting, you need a large number of procedures during your training (at least 75 carotid procedures during a two-year fellowship)," he said.
- "And then just to maintain your technical skill, you need to perform 50 stenting procedures per year."

...presented by Professor Carlo Setacci

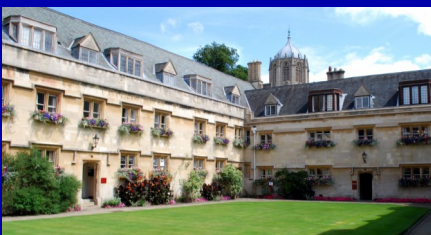
University of Siena, Italy



For Professor Setacci's full presentation, please visit the following link to the ACST-2 website:

<http://www.nds.ox.ac.uk/acst/acst-2-news/publications>

Collaborators Meeting 2014



18 –19th September 2014

Pembroke College, Oxford



At the ACST-2 Collaborators' Meeting there will be **prizes for recruitment**. Please continue to recruit as many patients as you can, and aim to achieve your recruitment targets before then!

...a final note from Luisa, your Recruitment Adviser

"Thank you for your continuous efforts and support in ACST-2. Keep up the great work and let's continue to make 2014 our **BEST** recruitment year ever!"

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