NIHR HTA/BUPA Foundation/University of Oxford

Asymptomatic Carotid Surgery Trial (ACST-2)

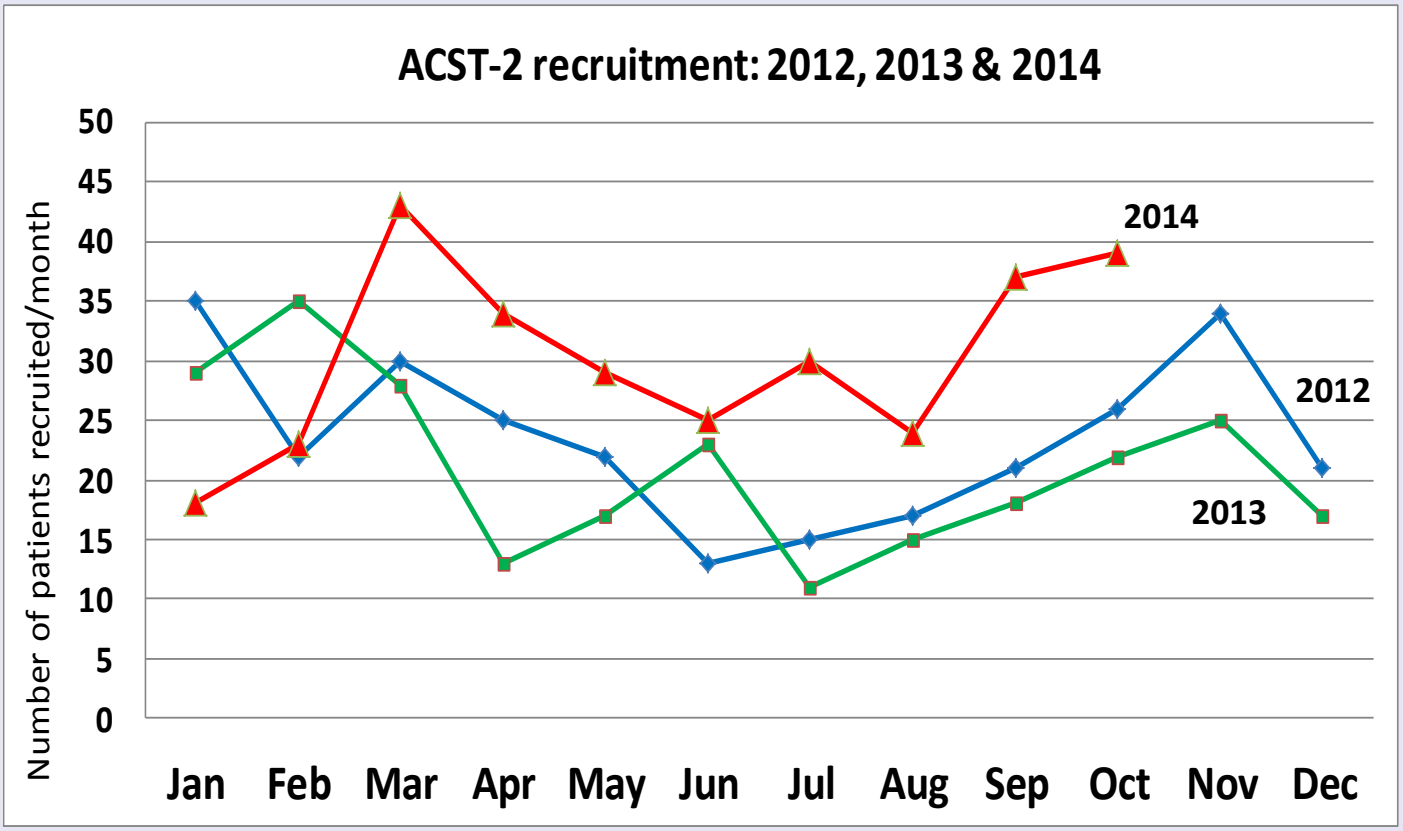
October Newsletter 2014

1,634 patients today!

Well done—we have recruited over 1600 patients!

October has been one of our best months with **39 patients** randomised. Thanks to you all for the amazing efforts in recruitment—keep going and recruit as many patients as you can!

With best wishes,
Alison Halliday, Richard Bulbulia, Richard Peto & the ACST-2 Team



See how everyone is recruiting ...

Please visit the ACST-2 website to view each centres' individual recruitment by clicking on the link below:

http://acst-2.org/Investigator%20Section/Recruitment%20Summary.html

NHS National Institute for Health Research

UNIVERSITY OF OXFORD

Novosibirsk recruits 1600th patient!

Congratulations to the **Novosibirsk Institute of Circulation Pathology** for randomising the ***1600th*** patient! Although only becoming active in February 2014, they have already randomised **25 patients** in the trial—very well done!

ACST-2 team and clinic at Novosibirsk Institute of Circulation Pathology, Russia

Dedinje has recruited over 100 patients!

ACST-2 team at Dedinje Cardiovascular Unit, Serbia

Congratulations to the ACST-2 team at **Dedinje Cardiovascular Unit** in Serbia: this centre has recruited **102 patients** for ACST-2 and are now **Diamond Recruiters!**

Well done and thank you for your efforts!

Istituto Auxologico— 168 patients recruited!

After 5 years of recruiting, Istituto Auxologico Italian won the award of **"Overall Top Recruitment Centre"** in ACST-2 . To view the full article, please click on the link below:

http://www.auxologico.it/2014/10/_overall_top_recruitment_center_/

2 NEW centers active since July

- **Mirano Hospital, Italy** (led by Dr Bernhard Reimers)
- **Royal Berkshire Hospital, UK** (led by Dr Enrico Flossmann)

>>> a very big welcome to the ACST-2 team! <<<

Collaborators' Meeting 2014

The ACST-2 Collaborators' Meeting (18th & 19th September 2014) at Pembroke College in Oxford, was a great success with excellent speakers . You can download photos and presentations from the event on the ACST-2 website: www.acst-2.org/.

Pembroke College Oxford - ACST-2 Collaborators' Meeting 2014

UK Stroke Club Conference

10-11th October 2014, Nottingham (UK)

UK Stroke Club Conference

ACST-2 attended the recent UK Stroke Club Conference in Nottingham, hosted by the **UK Stroke Association** and aimed for volunteers working in stroke clubs and groups from around the UK.

It was a privilege to spend 2 days with stroke survivors and learn more about what life is like for these patients after stroke. ACST-2 would like to congratulate the UK Stroke Association for hosting this special event.

1 in 5 strokes are caused by narrowing of the carotid artery.

Patients are now invited to join our Patient Advocacy Group at www.acst-2.org and participate in our online survey.

Stroke association

ACST-2 will also be attending the **UK Stroke Forum in Harrogate**

(2-4 December 2014) - *we look forward to seeing you there!*

UK STROKE FORUM Hosted by Stroke association

ACST-2 will be at the following meetings:

Vascular Society Annual Scientific Meeting, Glasgow

(26 - 28th November 2014)

UK Stroke Forum, Harrogate

(2-4th December 2014)

Munich Aortic & Carotid Conference (MAC) , Munich

(5-6th December 2014)

Controversies & Updates in Vascular Surgery (CACVS), Paris

(22nd-24th January 2015)

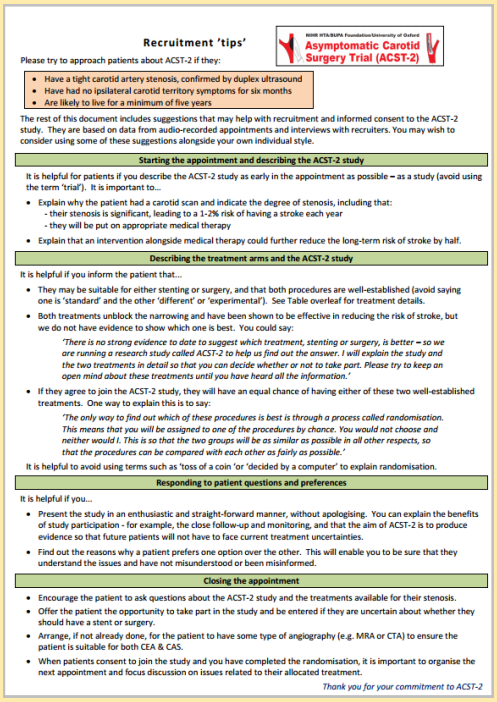
ACST-2 Recruitment 'tips'

...a note from Luisa, your Recruitment Adviser

"Please visit the ACST-2 website and download our latest Recruitment Tips document to help maximise recruitment in your centre!"

Email: luisa.teixeira@nds.ox.ac.uk

Telephone: +44 (0) 1865 223074



Recruitment 'tips'

Asymptomatic Carotid Surgery Trial (ACST-2)

Please try to approach patients about ACST-2 if they:

- Have a tight carotid artery stenosis, confirmed by duplex ultrasound
- Have had no ipsilateral carotid territory symptoms for six months
- Are likely to live for a minimum of five years

The rest of this document includes suggestions that may help with recruitment and informed consent to the ACST-2 study. They are based on data from audio-recorded appointments and interviews with recruiters. You may wish to consider using some of these suggestions alongside your own individual style.

Starting the appointment and describing the ACST-2 study

It is helpful for patients if you describe the ACST-2 study as early in the appointment as possible – as a study (avoid using the term 'trial'). It is important to...

- Explain why the patient had a carotid scan and indicate the degree of stenosis, including that:
  - their stenosis is significant, leading to a 1-2% risk of having a stroke each year
  - they will be put on appropriate medical therapy
- Explain that an intervention alongside medical therapy could further reduce the long-term risk of stroke by half.

Describing the treatment arms and the ACST-2 study

It is helpful if you inform the patient that...

- They may be suitable for either stenting or surgery, and that both procedures are well-established (avoid saying one is 'standard' and the other 'different' or 'experimental'). See Table overleaf for treatment details.
- Both treatments unblock the narrowing and have been shown to be effective in reducing the risk of stroke, but we do not have evidence to show which one is best. You could say:

  'There is no strong evidence to date to suggest which treatment, stenting or surgery, is better – so we are running a research study called ACST-2 to help us find out the answer. I will explain the study and the two treatments in detail so that you can decide whether or not to take part. Please try to keep an open mind about these treatments until you have heard all the information.'
- If they agree to join the ACST-2 study, they will have an equal chance of having either of these two well-established treatments. One way to explain this is to say:

  'The only way to find out which of these procedures is best is through a process called randomisation. This means that you will be assigned to one of the procedures by chance. You would not choose and neither would I. This is so that the two groups will be as similar as possible in all other respects, so that the procedures can be compared with each other as fairly as possible.'

It is helpful to avoid using terms such as 'toss of a coin 'or 'decided by a computer' to explain randomisation.

Responding to patient questions and preferences

It is helpful if you...

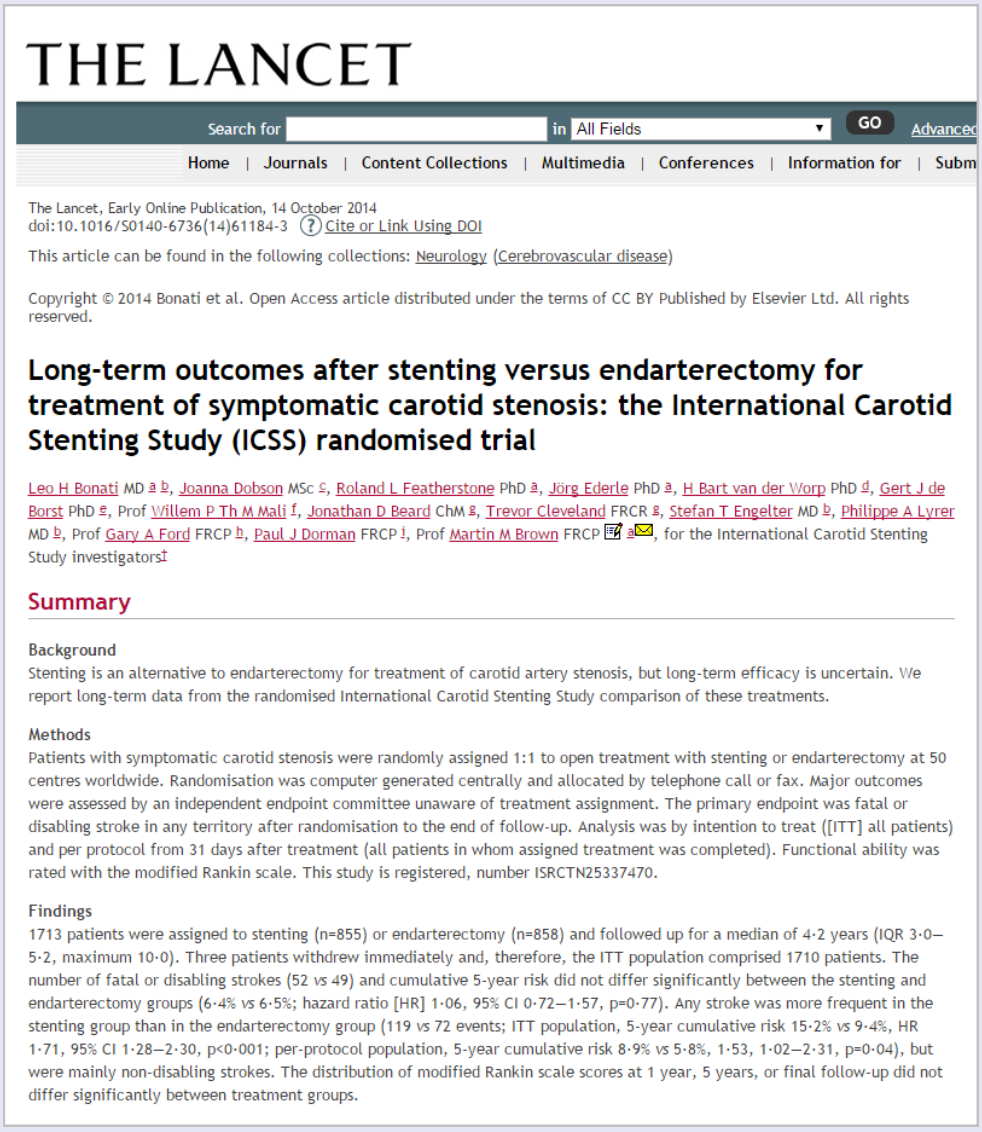
- Present the study in an enthusiastic and straight-forward manner, without apologising. You can explain the benefits of study participation - for example, the close follow-up and monitoring, and that the aim of ACST-2 is to produce evidence so that future patients will not have to face current treatment uncertainties.
- Find out the reasons why a patient prefers one option over the other. This will enable you to be sure that they understand the issues and have not misunderstood or been misinformed.

Closing the appointment

- Encourage the patient to ask questions about the ACST-2 study and the treatments available for their stenosis.
- Offer the patient the opportunity to take part in the study and be entered if they are uncertain about whether they should have a stent or surgery.
- Arrange, if not already done, for the patient to have some type of angiography (e.g. MRA or CTA) to ensure the patient is suitable for both CEA & CAS.
- When patients consent to join the study and you have completed the randomisation, it is important to organise the next appointment and focus discussion on issues related to their allocated treatment.

Thank you for your commitment to ACST-2

New research—IMPORTANT!



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This article can be found in the following collections: Neurology (Cerebrovascular disease)

Long-term outcomes after stenting versus endarterectomy for treatment of symptomatic carotid stenosis: the International Carotid Stenting Study (ICSS) randomised trial

Leo H Bonati MD [a b], Joanna Dobson MSc [c], Roland L Featherstone PhD [a], Jörg Ederle PhD [a], H Bart van der Worp PhD [d], Gert J de Borst PhD [e], Prof Willem P Th M Mali [f], Jonathan D Beard ChM [g], Trevor Cleveland FRCR [g], Stefan T Engelter MD [b], Philippe A Lyrer MD [b], Prof Gary A Ford FRCP [h], Paul J Dorman FRCP [i], Prof Martin M Brown FRCP [a], for the International Carotid Stenting Study investigators[†]

Summary

Background
Stenting is an alternative to endarterectomy for treatment of carotid artery stenosis, but long-term efficacy is uncertain. We report long-term data from the randomised International Carotid Stenting Study comparison of these treatments.

Methods
Patients with symptomatic carotid stenosis were randomly assigned 1:1 to open treatment with stenting or endarterectomy at 50 centres worldwide. Randomisation was computer generated centrally and allocated by telephone call or fax. Major outcomes were assessed by an independent endpoint committee unaware of treatment assignment. The primary endpoint was fatal or disabling stroke in any territory after randomisation to the end of follow-up. Analysis was by intention to treat ([ITT] all patients) and per protocol from 31 days after treatment (all patients in whom assigned treatment was completed). Functional ability was rated with the modified Rankin scale. This study is registered, number ISRCTN25337470.

Findings
1713 patients were assigned to stenting (n=855) or endarterectomy (n=858) and followed up for a median of 4·2 years (IQR 3·0–5·2, maximum 10·0). Three patients withdrew immediately and, therefore, the ITT population comprised 1710 patients. The number of fatal or disabling strokes (52 *vs* 49) and cumulative 5-year risk did not differ significantly between the stenting and endarterectomy groups (6·4% *vs* 6·5%; hazard ratio [HR] 1·06, 95% CI 0·72–1·57, p=0·77). Any stroke was more frequent in the stenting group than in the endarterectomy group (119 *vs* 72 events; ITT population, 5-year cumulative risk 15·2% *vs* 9·4%, HR 1·71, 95% CI 1·28–2·30, p<0·001; per-protocol population, 5-year cumulative risk 8·9% *vs* 5·8%, 1·53, 1·02–2·31, p=0·04), but were mainly non-disabling strokes. The distribution of modified Rankin scale scores at 1 year, 5 years, or final follow-up did not differ significantly between treatment groups.

The Long-term (4 years) results of ICSS

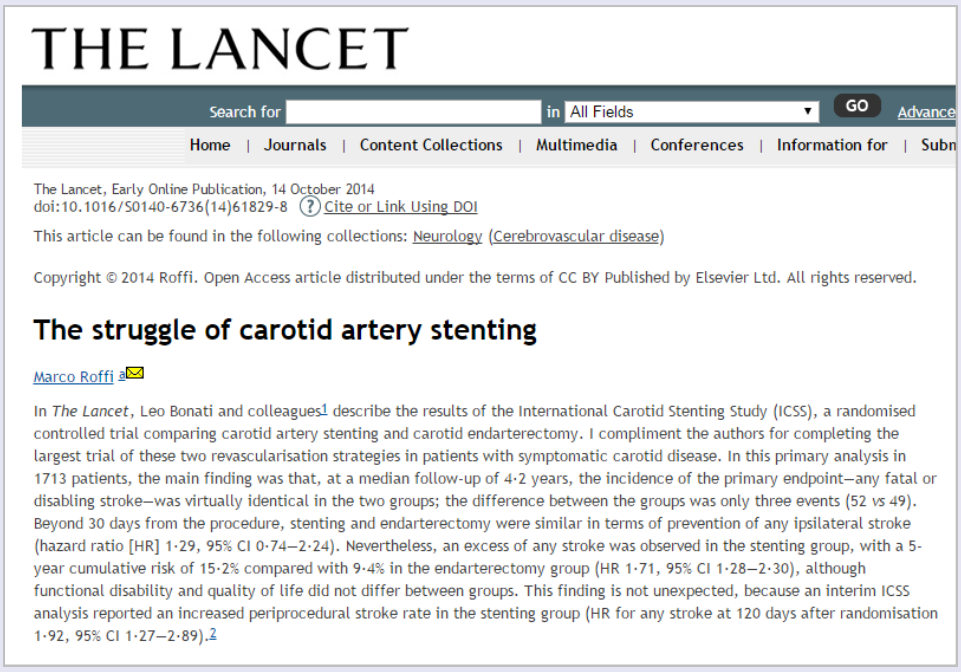
by *Bonati et al. 2014*

The results of the International Carotid Stenting Study (ICSS) were recently published in the Lancet by Bonati et al.

To view the full article, please click on the link below:

http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)61184-3/abstract/

The struggle of carotid artery stenting… by Marco Roffi



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This article can be found in the following collections: Neurology (Cerebrovascular disease)

The struggle of carotid artery stenting

Marco Roffi [a]

In *The Lancet*, Leo Bonati and colleagues[1] describe the results of the International Carotid Stenting Study (ICSS), a randomised controlled trial comparing carotid artery stenting and carotid endarterectomy. I compliment the authors for completing the largest trial of these two revascularisation strategies in patients with symptomatic carotid disease. In this primary analysis in 1713 patients, the main finding was that, at a median follow-up of 4·2 years, the incidence of the primary endpoint—any fatal or disabling stroke—was virtually identical in the two groups; the difference between the groups was only three events (52 *vs* 49). Beyond 30 days from the procedure, stenting and endarterectomy were similar in terms of prevention of any ipsilateral stroke (hazard ratio [HR] 1·29, 95% CI 0·74–2·24). Nevertheless, an excess of any stroke was observed in the stenting group, with a 5-year cumulative risk of 15·2% compared with 9·4% in the endarterectomy group (HR 1·71, 95% CI 1·28–2·30), although functional disability and quality of life did not differ between groups. This finding is not unexpected, because an interim ICSS analysis reported an increased periprocedural stroke rate in the stenting group (HR for any stroke at 120 days after randomisation 1·92, 95% CI 1·27–2·89).[2]

Dr Roffi discusses the recent ICSS results.

To view the full editorial by Dr Marco Roffi, please click on the link below:

http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)61829-8/fulltext