International Standard Randomised Controlled Trial Number: ISRCTN97744893

Centre Enrolment – Centre Personnel

Please refer to the protocol to check your centre has the required personnel to join ECST-2

(Please type or complete in CAPITAL LETTERS and ensure that the declaration on page 4 is signed)

Privacy and data protection statement: We ask you on this form to provide your address, telephone number and email address to the ECST-2 trial office. We will only use this information to contact you from time to time about the conduct of the trial (ECST-2) and its sub-studies, to inform you about meetings about the trial and to send you newsletters about the trial. Professor Martin M Brown, the Chief Investigator, will be responsible for the security of and access to the information which will only be accessed and used by members of the ECST-2 central office staff. This information is stored securely on our database. Individuals who cease working on the trial and no longer wish to receive our newsletters and other updates may opt-out of receiving these communications by contacting us at office@ECST2.com or writing to: The Trial Manager ECST-2, Box 6, The National Hospital, Queen Square, London WC1N 2BG, UK.

By what name would you like your centre to be known as on the trial database:

.....

Short name (if applicable).....

Name of Local Principal Investigator (Must be a consultant neurologist/physician or Surgeon listed below) :.....

Name of consultant neurologist/physician(s) randomizing and following up trial patients: (please copy and paste this section for each additional consultant neurologist/physician who will work in the trial)

Name……..

Department:……

Hospital/Centre name:……

Address:……

……..……

Telephone number:……..……
Fax number:……..……
Email Address:……..……
This person will be returning data on the ECST-2 website (delete as appropriate) Yes/No

Name of consultant surgeon(s) performing carotid endarterectomy (and audit data): (please copy and paste this section for each additional surgeon who will work in the trial)
NB The protocol states: "Centres will be required to submit documentation demonstrating the training and experience of their investigators, together with an audit of the outcomes of carotid revascularisation at their centre. A credentialing committee will be responsible for approving individual centre enrolment on the basis of this documentation and any other information requested by the committee. "

1. Name……..

Department:……

Hospital/Centre name:……

Address:……

……..

Telephone number:……..
Fax number:……..
Email Address:……..

Number of carotid endarterectomies performed in total: ____
Number of carotid endarterectomies performed as a consultant: ____
Number of carotid endarterectomies performed as a trainee (under supervision):_____

Number of carotid endarterectomies performed on average per year: ____

Number of non-fatal strokes within 30 days of treatment **(number of strokes/number of procedures audited)**: ___/___

Number of deaths (any cause) within 30 days of procedure **(number of deaths/number of procedures audited): _____/_____**

This person will be returning data on the ECST-2 website (delete as appropriate) Yes/No

Will stenting per performed at your centre ……Yes/No (delete as applicable)

If Yes complete the following section:

Name of consultant interventionist(s) performing stenting (with audit data)
(please copy and paste this section for each additional interventionist who will work in the trial)
NB the protocol states: "Centres will be required to submit documentation demonstrating the training and experience of their investigators, together with an audit of the outcomes of carotid revascularisation at their centre. A credentialing committee will be responsible for approving individual centre enrolment on the basis of this documentation and any other information requested by the committee. "

1. Name……..…….

Department:……

Hospital/Centre name:……

Address:……

……..……

Telephone number:…….……
Fax number:……..……
Email Address:…….……

Type of stent you propose to use in the trial (must be CE marked)……
Type of protection device you propose to use in this trial (must be CE marked if used)……

Number of carotid stents performed using the above named devices in total: _____
Number of carotid stents performed using the above named devices as a consultant: _____
Number of carotid stents performed using the above named devices as a trainee (under supervision): _____

Number of carotid stents performed on average per year: _____

Number of non-fatal strokes within 30 days of treatment **(number of strokes/number of procedures audited)**: ___/___

Number of deaths (any cause) within 30 days of procedure **(number of deaths/number of procedures audited): _____/_____**

This person will be returning data on the ECST-2 website (delete as appropriate) Yes/No

DECLARATION

The following neurologist/physician will be responsible for following up the patients:
Name……. Speciality……

The patients be followed up at the following location (e.g. of name department and hospital)……

1) One page CVs of principal investigator, interventionists and surgeons enclosed ☐
   (enclose long CV if one-page version not available)

2) Our centre performs 50 carotid endarterectomies per annum. ☐

3) We have a process for ensuring that the management of individual patients with carotid stenosis is routinely discussed between the neurologists or stroke physicians, surgeons, and radiologists or interventionists enrolling as investigators (e.g regular neurovascular meetings): ☐

4) Our centre is able to do MRI on trial patients ☐

5) We have access to (please tick one or both):
   1.5T MRI ☐
   3T MRI ☐

6) Our centre has the agreement of the Local Research Network (in the UK) to provide the necessary support to ensure the delivery of the study*** OR** ☐
   We have research staff employed on site to provide the necessary support to ensure the delivery of the study***** ☐

7) The above audit data is correct to the best of our knowledge**.** ☐

8) We have read the ECST-2 protocol and agree to abide by its requirements ☐

Signature of Principal Investigator

Print Name:……..

Signed:……. Date……

When you have heard from us that your centre has been approved by the Trial credentialing Committee you may begin the process of obtaining local local R&D/ethical approval. Once you have provided evidence of this to the trial office we will arrange a site initiation visit, after which you may commence randomizing.

Note: If you wish to nominate more than one neurologist/physician or more than two surgeons or interventionists please just duplicate the relevant pages of this form, but please also be aware that the credentialing committee of ECST-2 will consider if it is likely that enough procedures will be performed each year at a center to provide sufficient practice for the number of interventionists or surgeons nominated

***Complete details of research staff below and then return this form to the address at the end of page 6**

DETAILS OF ADDITIONAL STUDY PERSONAL.

If you have a research nurse, clinical research fellow, research practitioner or trial co-coordinator at your center that will be responsible for administrative matters relating to the study please give their details here:

Job Title:

Name…….. Department: ……...

Address:…….
Telephone number(s): ……
Fax number(s): ……
Email Address(s): ……
This person will be returning data on the ECSt-2 website (delete as appropriate) Yes/No

Job Title:

Name…….. Department: ……...

Address:…….
Telephone number(s): ……
Fax number(s): ……
Email Address(s): ……
This person will be returning data on the ECST-2 website (delete as appropriate) Yes/No