

# Cervical Artery Dissection In Stroke Study

## Standard Operating Procedure for Patient Recruitment & Randomisation

### Recruitment

1. Review inclusion/exclusion criteria as per protocol
2. Give patient the Patient Information Sheet
3. Obtain Informed Consent (1 original for CRF; 1 copy for patient notes; 1 copy for patient)



### Randomisation

1. Telephone Aberdeen randomisation service:  
**0800 387 4444**  
*Service requires: 4 digit centre ID code and initials*
2. Doctor to complete Entry Form and Drug Prescription Form for pharmacy
3. Insert prescription forms into drug chart if patient randomised to anticoagulant arm
4. Fax consent form and entry form to CADISS Office at St George's within 24 – 48h
5. Send GP letter
6. Download all images onto CD and send to CADISS Office

### Observation (non-randomised)

1. Doctor to complete Non-Randomised Entry Form and Ineligibility Form
2. Fax consent form and entry form(s) to CADISS Office at St George's within 24 – 48h
3. Send GP letter
4. Download all images onto CD and send to St George's



### 3 Month Follow-Up

1. Doctor to complete 3 month Follow-Up Form
2. Download all 3 month follow-up images onto CD and send to St George's
3. Inform patient that at 6 months and 1 year telephone follow-up will be undertaken by St George's

### SAE/SAR/SUSAR

Applicable to randomised patients only  
\*during 3 month clinical trial period\*

1. Doctor or designated person at centre to complete SAE/SAR Reporting Form within 24 h of being notified of event
2. Relate to Protocol and SAE/SAR SOP
3. Fax initial SAE/SAR Reporting Form to CADISS Office at St George's
4. CADISS Office and C.I. reviews and forwards to Sponsor
5. Complete SAE/SAR Reporting Form 7 days after initial event
6. Fax final SAE/SAR Reporting Form to CADISS Office at St George's

### Primary or Secondary Clinical Endpoints

Applicable to randomised  
and non-randomised patients  
\*for 1 year study period\*

1. Doctor or designated person at centre to complete Major Event Form or Drop Out Form
2. Fax form and send images (if completed) to CADISS Office at St George's

**NB** Please fax or send all data collection forms and images to:  
CADISS Office, Centre of Clinical Neuroscience, St George's University of London, Cranmer Terrace, London, SW17 0RE  
**Fax: 0208 725 2950**