Cervical Artery Dissection In Stroke Study

Submission date	Recruitment status No longer recruiting	Prospectively registered	
04/03/2007		[X] Protocol	
Registration date	Overall study status Completed	Statistical analysis plan	
18/05/2007		[X] Results	
Last Edited	Condition category	[] Individual participant data	
27/02/2019	Circulatory System		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00238667

Protocol serial number

Protocol version 8.1 (19th January 2010)

Study information

Scientific Title

Cervical Artery Dissection In Stroke Study

Acronym

CADISS

Study objectives

Is therapy with anticoagulants better than treatment with antiplatelet agents for acute cervical artery dissection?

On 26/05/10 this record was updated to include changes in the protocol from v.3 (2007) to v.8.1 (2010). All updates can be found in the relevant field with the above update date. Please also note that the overall trial end date was changed from 01/01/10 to 31/12/11.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South West London 3 Research Ethics Committee (formerly known as Wandsworth REC), 22/12/2004, ref: MREC 04/Q0803/215

Study design

Randomised multicentre open treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stroke, carotid artery dissection and vertebral artery dissection

Interventions

This trial is currently recruiting in the United Kingdom as of 04/03/2007 - planning to extend internationally.

Patients will be randomised to either antiplatelet or anticoagulation therapy initially for at least 3 months, and thereafter at the discretion of the attending physician.

Arm 1: Antiplatelet therapy: Aspirin, dipyridamole or clopidogrel alone or in dual combination. Arm 2: Anticoagulation with heparin (intravenous adminsitration, either unfractionated heparin or a therapeutic dose of low molecularweight heparin) followed by warfarin administered orally aiming for an coagulant response time (INR) in the range 2-3. Local protocols for heparin therapy can be used.

Treatment will be open-label. Low dose heparin prophylaxis for prevention of Deep Vein Thrombosis (DVT) is not a contra-indication, but its use should be recorded. Such prophylaxis may be continued after randomisation in the antiplatelet arm at the discretion of the local clinician. The doses of each drug used for antiplatelet therapy will be according to physician preference.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

anticoagulants, antiplatelet agents

Primary outcome(s)

Time to first ipsilateral stroke or death (any cause) within 3 months from randomisation

Key secondary outcome(s))

The following will be measured at the 3-month follow up:

- 1. Ipsilateral TIA, stroke or death (any cause) within 3 months from randomisation
- 2. Any TIA and stroke
- 3. Any stroke
- 4. Major bleeding
- 5. Presence of residual stenosis at 3 months (>50%)
- 6. Mortality

Completion date

31/12/2011

Eligibility

Key inclusion criteria

- 1. Extra cranial carotid or vertebral artery dissection with symptom onset within the last 7 days. This includes:
- 1.1. Ipsilateral Transient Ischemic Attack (TIA) or stroke with known date of onset
- 1.2. Ipsilateral Horner's syndrome or neck pain with known date of onset
- 2. Imaging evidence of definite or probable dissection on Magnetic Resonance Imaging (MRI)/ Magnetic Resonance Angiography (MRA), Computed Tomographic Angiography (CTA) or ultrasound (patients can be initially randomised on ultrasound alone but subsequent MR or CTA confirmation is needed)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

- 1. Intracranial cerebral artery dissection
- 2. Symptom onset >7 days

- 3. Contraindications to either antiplatelet agents or anticoagulation therapy, including active peptic ulceration, bleeding peptic ulcer within 1 year
- 4. Patient refusal to consent
- 5. Patients already taking antiplatelets or anticoagulants for other reasons e.g. prosthetic heart valves in whom the treatment cannot be replaced by either antiplatelets or anticoagulants 6. Women who are pregnant

Added 26/05/10:

7. latrogenic induced dissection

Date of first enrolment

01/04/2006

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Centre for Clinical Neuroscience London United Kingdom SW17 ORE

Sponsor information

Organisation

St George's University of London (UK)

ROR

https://ror.org/040f08y74

Funder(s)

Funder type

Charity

Funder Name

Stroke association (UK)

Alternative Name(s)

TheStrokeAssociation, TheStrokeAssoc

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	non-randomised arm results	14/08/2012	Yes	No
Results article	results	01/04/2015	Yes	No
Results article	results	01/06/2019	Yes	No
Protocol article	protocol	01/11/2007	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes
Study website	Study website	11/11/2025 11/11/2025	No	Yes