Cervical Artery Dissection In Stroke Study

Submission date 04/03/2007	Recruitment status No longer recruiting	[[X
Registration date 18/05/2007	Overall study status Completed	[[X
Last Edited 27/02/2019	Condition category Circulatory System	

-] Prospectively registered
- K] Protocol
-] Statistical analysis plan
- X] Results
- on category [] Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.dissection.co.uk/

Contact information

Type(s) Scientific

Contact name Prof Hugh Markus

Contact details

Centre for Clinical Neuroscience St George's University of London Cranmer Terrace London United Kingdom SW17 0RE

hmarkus@sgul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT00238667

Secondary identifying numbers

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

Secondary study design Randomised controlled trial

Study setting(s) Not specified

Study type(s) Treatment

Participant information sheet

Patient information can be found at: http://www.sgul.ac.uk/dms /32EE671CBC5FEBFFE9794FC111A6BA0D.pdf

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 measure

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

Secondary outcome measures

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

Overall study start date 01/04/2006

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

Age group

Not Specified

Sex

Both

Target number of participants

250 in feasibility phase

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 England

United Kingdom

Study participating centre Centre for Clinical Neuroscience

Centre for Clinical Neuroscience London United Kingdom SW17 0RE

Sponsor information

Organisation

St George's University of London (UK)

Sponsor details

Research and Development Office St George's University of London Cranmer Terrace London England United Kingdom SW17 0RE -

cadiss@sgul.ac.uk

Sponsor type University/education

ROR https://ror.org/040f08y74

Funder(s)

Funder type Charity

Funder Name Stroke association (UK)

Alternative Name(s)

Funding Body Type Private sector organisation

Funding Body Subtype Associations and societies (private and public)

Location United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	01/11/2007		Yes	No
Results article	non-randomised arm results	14/08/2012		Yes	No
Results article	results	01/04/2015		Yes	No
<u>Results article</u>	results	01/06/2019		Yes	No