The 2nd European Carotid Surgery Trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON46858

Source
ToetsingOnline

Brief title
ECST-2

Condition

- Central nervous system vascular disorders

Synonym
carotid narrowing; atherosclerotic carotid artery stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: carotid artery, carotid stenosis, endarterectomy, stroke

Outcome measures

Primary outcome

Any stroke at any time, plus non-stroke death occurring within 30 days of

revascularisation

Secondary outcome

- Ipsilateral stroke

- myocardial infarction or any hospitalisation for

- vascular disease during follow up.

- Disabling stroke during follow up.

- New cerebral infarction or haemorrhage on post procedural MRI.

- Cognitive impairment.

- Further treatment procedure.

- Adverse events attributed to medical treatment or CEA.

- Quality of life and economic measures.

Study description

Background summary

Randomized trials have established the benefit of revascularisation by carotid endarterectomy (CEA) for moderate and severe carotid stenosis. However, a risk model derived from one of these trials and validated in another, showed that only patients with a high risk of stroke under medical therapy benefited from CEA. For a large range of patients there was neither clear benefit nor harm from CEA. Medical therapy for stroke prevention has improved since these original trials, with more widespread use of statins, more active lowering of blood pressure and more effective antiplatelet regimes. Lower optimum targets have been set for risk factor control e.g. blood pressure. Therefore CEA may not be beneficial in many patients with carotid stenosis treated with modern optimized medical therapy (OMT).

Study objective

The aim of ECST-2 is to determine the best current regime for treating patients with asymptomatic and symptomatic carotid stenosis who are at intermediate and lower risk of stroke. Our main hypothesis is that patients who have clinical characteristics that predict a 5-year risk of future stroke of <15% when treated with modern optimized medical treatment (OMT) alone, will not benefit from early revascularisation in addition to OMT, because any reduction in future stroke rates after revascularisation will be balanced by an excess of procedural stroke and death.
We propose that in the future it would be better if patients were routinely selected for revascularisation on the basis of a detailed, up to date risk assessment taking into account all the known risk factors.

Study design

ECST-2 is a multicentre, randomised, controlled, open, prospective clinical trial with blinded outcome assessment. We will use a risk model based on clinical characteristics to calculate a 5-year Carotid Artery Risk (CAR) score, which will stratify patients as at high risk (>15%), intermediate risk (7.5-15%), or low risk (<7.5%) of future stroke using predictive data from previous trials. An interim analysis using MRI to determine rates of cerebral infarction and haemorrhage at 2 years after randomisation will be performed to assess safety and feasibility of the design and inform the design and sample size calculations for the full trial.

Intervention

carotid revascularisation (endarterectomy or, in exceptional cases, stenting) + medication vs medication alone

Study burden and risks

The trial compares two existing forms of treatment currently used in many hospitals. Hence, the trial is not an industry sponsored test of a new treatment with unknown hazards. The trial protocol anticipates that some patients may be harmed inadvertently as a result of revascularisation in the trial and OMT is not expected to prevent all vascular events. Indeed, the determination of the rate of these outcome events is a major aim of the trial. However, we believe that the risks of these adverse events will be outweighed by the benefits of treatment in either arm of the trial. The trial protocol does not subject patients to hazards that the patient would not have encountered if they had received the trial treatments outside the context of the trial in routine practice.

In the first year after randomisation there will be four contact moments in the

AMC and one short telephone interview. After the first year there will be a visit to the AMC once a year, with a minimum of 5 years and a maximum of 10 years. At each visit there will be blood withdrawal, carotid ultrasound, physical examination and measurement of blood pressure. During the study a patient will have three MRI's and three short memory tests and health questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- > 18 years of age
- symptomatic or asymptomatic atherosclerotic carotid stenosis equivalent to at least 50% measured using de NASCET method
- CAR (carotid artery risk) score < 15% 5-year risk

- clinicians are uncertain about which treatment modality is best for the individual patient

Exclusion criteria

- Modified Rankin score > 2
- previous endarterectomy or stent in the randomised artery
- coronary artery bypass grafting within 3 months prior to randomisation or other major surgery within 6 weeks prior to randomisation
- coronary artery bypass grafting or other major surgery planned within 6 weeks randomisation
- pregnancy
- life expectancy of less than two years due to a pre-existing condition e.g. cancer.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-11-2014
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	25-09-2013

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Not approved Date:	27-09-2016

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ISRCTN	ISRCTN-97744893
CCMO	NL41785.018.13