Evaluation of Secondary Prevention of Stroke Study in the Outpatient Clinic

Published: 02-11-2011
Last updated: 30-04-2024

The main objective of this study is to determine if the SPC has added benefits in optimising risk factors to prevent recurrent stroke, as compared with secondary prevention performed by the GP.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON35302

Source
ToetsingOnline

Brief title
ESPRESSO

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident, Stroke

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Secondary prevention, Stroke

Outcome measures

Primary outcome

The primary outcome is a composite score on a newly proposed

stroke-prevention-scale. This composite score will be calculated based on the

presence or absence of the risk factors and the established relative risk (RR)

as published in the literature.

Secondary outcome

1. Stroke caused by subarachnoidal haemorrhage or cerebral venous sinus

thrombosis

2. Dissection of the carotid artery (these patients have no cardiovascular risk

factors for stroke recurrence)

3. No informed consent obtained

Study description

Background summary

Stroke is the main cause of disability in high-income countries and ranks second as cause of death worldwide. Recurrent stroke occurs in about 26% of the patients within 5 years. It is therefore crucial to pay attention to minimizing the risk of recurrence. Several risk factors for recurrent stroke can be directly influenced: smoking, hypertension, hypercholesterolemia and diabetes. Treatment of these modifiable risk factors has been shown to reduce the risk of stroke and is known as *secondary prevention*.

To date, in routine clinical practice, the general practitioner (GP) takes care of secondary prevention. However, the degree to which secondary prevention is practiced depends on the dedication of the GP and the compliance of patients, is not standardised and might have considerable variability between different

GP*s. In order to standardise the secondary prevention and possibly improve treatment of previous mentioned risk factors, the Department of Neurology at the Academic Medical Center (AMC) has recently started a specific outpatient clinic, known as the *secondary prevention clinic* (SPC), as a clinical routine. The present study will investigate if the initiation of this SPC has larger effects on reducing the risk factors of stroke, as compared with secondary prevention performed by the GP. When results of the present study (phase I) show in superior treatment of risk factors, a randomised trial to investigate the effect of SPC on clinical outcomes (recurrent stroke) will be planned in the near future (phase II).

Study objective

The main objective of this study is to determine if the SPC has added benefits in optimising risk factors to prevent recurrent stroke, as compared with secondary prevention performed by the GP.

Study design

We will conduct a prospective sequential comparison study. Consecutive patients treated with the SPC protocol will be compared with historical controls: patients treated with *standard care* by the GP, as was considered *usual care* before initiation of the SPC.

Intervention

Standardized, regular check ups during one year after the initial event, performed at the SPC in our outpatient neurology department.

Study burden and risks

Main goal of the SPC is to reduce the number of stroke recurrences through regular monitoring of the lifestyle of a patient who has suffered a stroke, in an active and standardized way. Since February 2011, all consecutive stroke patients in our department are referred to the SPC when *regular follow-up* in the acute phase of a stroke has been completed. For patients *regular follow-up* comprises of a possible hospital admission, initiation of treatment for stroke, and a single follow-up visit to a neurologist at the outpatient clinic two weeks after the initial event.
At the SPC, a blood sample will be taken to (re)evaluate fasting glucose and cholesterol. In addition, patients will be asked to fill in a questionnaire to gain insight in a patient*s lifestyle, and the blood pressure will be measured during 30 minutes (Dynamap). After the intake and assessment of the personal risk profile of a patient, a *risk reduction plan* will be made in consultation with the patient. Patients will be followed for one year to actively encourage them to work on their risk plan and to set up new goals.

The *personal risk profile* will also be made for the patients from the control group. In the single visit to the SPC, one year after the stroke, the same procedures will take place to assess the personal cardiovascular risk profile, as will be performed in stroke patients nowadays.

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

1. Age at least 18 years
2. Stroke (ischemic or haemorrhagic)
3. Visitor of the AMC outpatient clinic

Exclusion criteria

1. Stroke caused by subarachnoidal haemorrhage or cerebral venous sinus thrombosis
2. Dissection of the carotid artery (these patients have no cardiovascular risk factors for stroke recurrence)
3. No informed consent obtained

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2011
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	02-11-2011
Application type:	First submission
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
CCMO	NL38035.018.11