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Second Manifestations of ARTerial disease (SMART) study: Rationale and design

P.C.G. Simons[1], A. Algra[1,2], M.F. van de Laak[1], D.E. Grobbee[1] & Y. van der Graaf[1], for the SMART study group*

[1]*Julius Center for Patient Oriented Research,* [2]*Department of Neurology, University Medical Center, Utrecht, The Netherlands*

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Abstract. The Second Manifestations of ARTerial disease (SMART) study is a single-centre prospective cohort study among patients, newly referred to the hospital with (1) clinically manifest atherosclerotic vessel disease, or (2) marked risk factors for atherosclerosis. The first objectives of the SMART study are to determine the prevalence of concomitant arterial disease at other sites, and risk factors in patients presenting with a manifestation of arterial disease or vascular risk factor and to study the incidence of future cardiovascular events and its predictors in these high-risk patients. At least 1000 patients, aged 18 to 80 years, will undergo baseline examinations, including a questionnaire on cardiovascular disease, height, weight and blood pressure measurements, blood tests for glucose, lipids, creatinine and homocysteine, urinary tests for microproteinuria, resting twelve-lead electrocardiogram, ultrasound scanning of the abdominal aorta, kidneys and the carotid arteries, measurements of common carotid intima-media thickness and arterial stiffness, and a treadmill test to assess atherosclerosis of the leg arteries. Abnormal findings are reported to the treating specialist and general practitioner with a treatment suggestion according to current practice guidelines. Recruitment and baseline examinations began in September 1996. All cohort members will be followed for clinical cardiovascular events for a minimum of three years. In the scope of secondary prevention, the study is expected to support the design of solid based screening and treatment programmes and evidence-based cardiovascular medicine to reduce morbidity and mortality, and improve quality of life, in high-risk patients.

Key words: Atherosclerosis, Cardiovascular disease, Cohort study, Risk factors, Secondary prevention

Introduction

Cardiovascular disease is still a major cause of morbidity and mortality in industrialised countries. It affects large numbers of people and has a major impact on quality of life. Primary prevention is important to reduce early morbidity and mortality. After a first manifestation of cardiovascular disease there is an increased risk for recurrence at the same or at another location in the vascular bed, because atherosclerosis is a progressive and generalized process. In these patients it is important to retard the atherosclerotic process to prevent further morbidity and mortality (secondary prevention). Risk factors should be detected and treated [1]. It is at present unknown whether detection and treatment of asymptomatic atherosclerotic lesions will improve overall prognosis. The Second Manifestation of ARTerial disease (SMART) study was designed to focus on the prevalence and incidence of additional cardiovascular disease in patients who have already a manifestation of arterial disease or who are otherwise at a high risk to develop symptomatic arterial disease.

Objectives

The aims of the SMART study are four-fold:

1. To determine the prevalence of concomitant asymptomatic arterial disease and risk factors in patients presenting with a manifestation of arterial disease or risk factor.
2. To study the incidence of future cardiovascular events and its predictors in these high-risk patients.
3. To study the effectiveness of detection and treatment of concomitant asymptomatic arterial disease and risk factors in these patients on cardiovascular morbidity and mortality and quality of life.
4. To attain protocolized multidisciplinary care for the cardiovascular patient.

Rationale

Atherosclerosis is a progressive disease affecting all arteries. A clinical manifestation of atherosclerotic

* Members of the SMART study group are listed in the Appendix.