Utrecht Cardiovascular Cohort - The Second Manifestations of ARTerial disease Study

Published: 05-11-2014
Last updated: 24-04-2024

The purpose of UCC-SMART is to create multidisciplinary care of patients with cardiovascular disease and to create at the same time, by building a vascular cohort, a scientific infrastructure. The main questions of UCC-SMART are:* What is the risk...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON54646

Source
ToetsingOnline

Brief title
UCC-SMART

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Myocardial infarction, Stroke, Vascular disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: arterial disease, prediction, secondary prevention

Outcome measures

Primary outcome

"Endpoints" are unwanted vascular complications, which should be prevented by the treatment given to the patient.

Possible endpoints which are reported in the six months follow-up are objectified by requesting clinical information of the treating specialist or GP. Each reported endpoint follows an verification procedure. All data of that endpoint are presented independently to three members of the endpoint committee. Each member gives a classification to the endpoint and the classifications are compared. If the members disagree, that particular endpoint will be discussed with the principal investigators.

The endpoints are:

• Stroke

• Myocardial infarction

• Heart failure

• Amputation

• aortic rupture

• Vascular Intervention

• Vascular Intervention of an intracranial aneurysm

• ESRD

• Bleeding

• Retinal haemorrhages and infarctions

• Diabetes

• Dementia

• Death

Secondary outcome

not applicable

Study description

Background summary

The prognosis of patients with vascular disease or vascular risk factors is largely determined by the progression of atherosclerosis. Therefore patients with symptomatic vascular disease are treated for multiple purposes: to improve vascularization to the specific organs and to improve the traditional risk factors, reducing morbidity and mortality caused by cardiovascular disease. The traditional risk factors (smoking, cholesterol, hypertension) can only partially predict the prognosis of the individual patient. Other factors which may contribute to the progression of atherosclerosis in patients with clinically manifest vascular disease are hardly known.

In 1996 the Second Manifestations of ARTerial disease (SMART) study was started at the University Medical Centre Utrecht (UMCU). This study started solely as a research study and was independent of patient care. Later, in 2002, SMART was fully integrated into patient care and since that time it consists of two parts: 1) a patient care component and 2) a scientific component. These two components are not always strictly seperated. For example, sometimes for the scientific research data is used from patient care. But when a tumor of the kidney is found by an abdominal ultrasound, the treating physician and the patients will be informed immediately.

Patients visiting the UMCU for the first time with a TIA (transient ischemic attack), stroke, carotid stenosis, peripheral vascular disease, aneurysm abdominal aorta, angina pectoris, myocardial infarction, renal insufficiency, diabetes mellitus, hyperlipidemia, hypertension, HIV, preeclampsia and intrauterine growth retardation in the past, will be asked to participate in the UCC-SMART Study and are offered the patient care part and the scientific part.

Study objective

The purpose of UCC-SMART is to create multidisciplinary care of patients with cardiovascular disease and to create at the same time, by building a vascular cohort, a scientific infrastructure.

The main questions of UCC-SMART are:
* What is the risk profile of patients at high cardiovascular risk and what is the interdependence of these risk factors?
* What factors predict morbidity, mortality and diabetes in a high-risk population and what are the differences between different vascular beds and risk factors?
* What is the additional prognostic value of new cardiovascular risk factors (genes, exosomes, adipokines, coronary calcium and other imaging parameters) for new vascular events and mortality?
* Does the use of the UCC-SMART risk score (risk mapping, multidisciplinary therapy advice) improve patient care?

To answer many scientific questions results of new tests that have not been entered are neccessary as well as data from patient care
Other scientific questions are elaborated in various substudies.

Study design

UCC-SMART is an ongoing prospective cohort study. All included patients are asked to complete a questionnaire annually. The treating physician carries out the examinations he or she considers to be neccessary for the primary visit. Subsequently the research nurse or doctor's assistent approaches, orally or in writing, the patient to participate in UCC-SMART. After approval an appointment will be made to perform the remaining tests.
The studies take a total of 3 hours and are all performed at the same morning. First, fasting blood samples and a urine portion of the patient will be obtained. After this, in the radiology department, multiple tests will be performed. Next an ECG will be made, after this a CT scan.

The inclusion of patients is largely delegated to the cooperating divisions (vascular center, vascular medicine, infectious diseases, neurology, obstetrics, cardiology and cardiac surgery) each following their own procedures. To detect patients with clinically manifest disease, EZIS is used. These patients receive, after an appropiate waiting time, the information leaflet of SMART. If the patient is interested, he or she will send the signed informed consent back to the SMART office. A nurse of the SMART office will contact the patient by telephone and checks whether all information is clear. The patients are given the opportunity to ask questions and after this an appointment for the screening will be made.

Nature of investigations
The following studies are carried out in the framework of UCC-SMART :
* A questionnaire on heart disease in which the following types of questions are discussed. The questions are as follows: 1. General | 2. Familiy history of cardiovascular disease | 3. Heart | 4 Brains | 5. Legs | 6. Blood pressure, diabetes , cholesterol | 7. use of oral contraceptives, menstruation, pregnancy | 8. Smoking, alcohol, nutrition | 9. Physical exercise | 10. Quality of life .

Several risk factors are determined:
• blood pressure
• height, weight , waist and hip
• Hb , Ht
• total cholesterol , triglycerides, HDL-C, LDL-C, (fasting) glucose and HbA1c
• TSH and Insulin
• HsCRP
• Apo B
• serum creatinin, microalbuminuria and creatinin
•Troponin
•NT-pro-BNP
•Plateletfunction
•Insulin
•GWAS
* The screening conducted studies / measurements :
• Ultrasound of the abdomen, with the questions: abdominal aortic aneurysm (max. AP diameter juxta -renal and infra -renal aortic) and kidney atrophy (kidney length and volume) bilaterally
• duplex examination of the carotid arteries on both sides, to show a carotid stenosis
• the ankle - brachial index at rest for diagnosis of peripheral artery disease
• intra-abdominal fat with ultrasound
• a 12-lead electrocardiogram
• CT scan of heart and neck vessels

* Of all patients in the UCC-SMART cohort the biological material is stored . Blood is stored in -80 ° C freezers, in the form of serum, citrated plasma, EDTA - plasma and packed red cells. Urine is stored in normal form and in acidified (pH = 2-3) frozen form and stored at -20 º C. DNA is isolated and stored .

If the ultrasound examinations, ECG or the EAI are performed less than a half year ago or a CT scan of the heart and neck vessels was made less than a year ago in the UMCU, those results will be acquired. If the treating physician requests tests which are included in the SMART screening these results will be used. Sometimes a is patient included in the UCC-SMART study after the second visit to the treating physician. Results of the laboratory tests closest to the first clinic visit will be collected to avoid influence of already established therapy.

Therapy advice
The screening results will be collected the same day and prepared for the therapeutic advice. In a multidisciplinary advisory committee, under the responsibility of a vascular internist, a definitive treatment advice is formulated. This committee meets once a week.
To formulate the therapeutic advice the multidisciplinary guideline Cardiovascular riskmanagement is used. For blood pressure, this means that a maximum value of 140/90 mmHg is accepted.
The cholesterol policy depends on the absolute 10-year risk of the patient. If LDL > 2.5 mmol / l with a low absolute 10-year risk of 10 %, LDL reduction is not recommended. With a high absolute risk (> 20 %), it is recommended to lower LDL. With an absolute 10-year risk between 10-20 % the cholesterol policy depends on other risk factors as recommended in the guidelines. In diabetic patients and glucose abnormalities the ADA guidelines are consulted.
In case of an abnormal ankle-brachial index, the guidelines peripheral vascular disease will be used. For smoking and obesity, lifestyle advices will be given.
If a carotid stenosis >70% is determined by duplex the patient will be, in consultation with the treating physician, referred to a neurologist.
The therapy advice will be send to the referring specialist or the GP. The patient receives a summary of the results of the screening, also stating which attention and / or treatment is needed: the so-called personal screening profile. Results falling in the normale range and not judged by the vascular team as abnormal, will not be listed in the screening profile. The time period between screening and completion of the screening profile is 1.5 - 2 weeks.

Follow-up
All patient in the cohort will be followed. This means that of all patients in the UCC-SMART cohort the occurence of new vascular events is accurately recorded. The patient is approached once a year with a short questionnaire whether he / she has been hospitalized and whether in the past year diabetes mellitus or dementia has been diagnosed. If a vascular complication has occured, this will be further investigated. At the beginning of the study the patients are asked to inform the SMART office in case of rehousing. If patients find the follow-up to burdersome, possible endpoints will be collected via the GP.

Study burden and risks

The burden of patients for participating in the study is the time needed for all examinations. In contrast, the patients receive a structured therapeutic advice

Adverse events
Complications caused by an examination of the UCC-SMART study is reported according to the appropriate channels (MIP). Endpoints are not considered adverse events because in UCC-SMART no experimental interventions take place.

Incidental and secondary findings
Incidental findings are often detected by the staff of the radiology department. If an incidental finding is found, the UCC-SMART doctor is informed. Findings found with an ultrasound are discussied with the radiologist. The radiologist determines further management (supplementary investigations or other follow-up). Every incidental finding will be recorded in the file of the patients. Uncomplicated cysts and known abnormalities do not require consultation.

If abnormalities are found, such as aneurysm of the abdominal aorta >3.5cm, abnormal blood tests or ECG abnormalities with clinical consequences, the SMART doctor is always informed and the SMART doctor presents the found abnormalities to the appropiate specialist from the UCC-SMART study and the treating physician to determine further management. The SMART doctor does not discuss findings directly with the patient. A short report of the findings and consequences will be made by the SMART doctor and will be send to the treating physician and the GP.

The following guidelines concerning incidental findings are followed:
- only inform the patient about incidental findings if therapeutic consequences are neccessary
- advice on the incidental finding and possible therapeutic consequences will be sought by relevant experts
- Incidental findings are well communicated to the specialist or GP
- All findings and actions are documented in the status of the patient

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Stroke or TIA
Myocardial Infarction
PTCA
Hypertension
Hyperlipidemia
Aorta aneurysm
Diabetes
Pre-eclampsia and premature birth in history
HIV

Exclusion criteria

pregnancy
Rankin >3
life-expectancy less than 1 year

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-11-2014
Enrollment:	16227
Type:	Actual

Ethics review

Approved WMO Date:	05-11-2014
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	20-04-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-01-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-08-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-07-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NL45885.041.13