

Population Screening Act: research into calcium score and risk of cardiovascular disease

No. 2017/19

Executive summary

Health Council of the Netherlands



As part of the long-term population study ERGO, Erasmus Medical Centre (Erasmus MC) in Rotterdam aims to conduct scientific research into the effect of atherosclerosis on the risk of cardiovascular disease. The research design of this sub-study requires a permit from the Minister of Health, Welfare and Sport (VWS) based on the Population Screening Act (WBO). The Population Screening Committee of the Health Council has examined the permit application to the WBO and has advised the State Secretary to grant the permit under a number of conditions.

Permit application

The aim of the proposed study is to investigate how atherosclerosis has developed over ten years. The applicant would like to investigate which factors affect the increase or stabilisation of atherosclerosis. After that, for five years, it would like to follow the clinical consequences of increase or stabilisation for the risk of a heart attack or stroke. This study will be conducted as part of the Rotterdam study (ERGO), a

prospective cohort study in the Rotterdam district of Ommoord.

A previous study within ERGO was conducted between 2003 and 2006. At that time, CT scans were used to measure atherosclerosis in 2,500 people. Now, more than ten years later, the participants who were scanned between 2003 and 2006 and are still alive will be invited again for CT scans. Approximately 1,900 men and women with an average age of 79 years are involved. The new CT scans will be compared with the prior CT scans to assess potential changes in atherosclerosis during the past ten years. Changes or stabilisation will then be related to any heart attacks or strokes occurring in the next five years (prospective study).

Review against WBO requirements

Scientific validity

The Committee takes a positive view of the scientific validity of the proposed study. The measuring method with CT scan is adequate, the research design is satisfactory and the

expected number of participants has sufficient statistical power of expression.

Benefit-risk balance

The benefit of the proposed research is that it provides scientific knowledge on risk factors for heart attacks and strokes. Since ionising radiation is used, the study carries risks for the health of the participants. However, the Committee notes that the maximum dose of radiation in the proposed study is well within the permissible limits, given the purpose of this study and the average age of the participants. Another risk is that the CT scan may reveal findings that are not related to the study according to the research questions. For example, not only atherosclerosis but other disorders (such as tumours or benign abnormalities) of the lungs or the liver may also be seen on the CT scan. These types of findings are referred to as incidental findings, provided they are found 'spontaneously', thus found inevitably with the disorders sought. In some cases such findings may be beneficial for the



participants, but in general the Health Council believes that incidental findings should be considered disadvantageous. For example, they may lead to (unnecessary) anxiety or to stressful and risky follow-up tests and treatments. The proposed study is designed so that all CT scans are assessed within two weeks for findings other than those directly related to the research question. The Committee notes that, this constitutes no incidental findings (abnormalities found spontaneously), but an additional form of screening, specifically the active detection of disorders or abnormalities that are not related to the research question. When actively sought for, the chance of discovering other findings is even greater than with incidental findings, which makes the disadvantages of incidental findings even more prominent.

The Committee believes that the scientific benefit of the proposed sub-study clearly outweighs the risks for the individual participants, provided that abnormalities are not

actively sought for outside the scope of the research questions.

Rules for medical treatment

It is important for participants to be well informed in advance about the scientific purpose of the study and its risks, particularly about the radiation risk and the risk of incidental findings. According to the Committee, regardless of the height the calcium score does not provide clinically useful information for the participants of this particular study. However, on request the participant (and possibly the general practitioner) may be informed about his calcium score, but only as possibly interesting research information. The Committee believes that the information leaflet and the consent form are incomplete and not entirely comprehensible.

Advice

The Committee advises granting a permit for the study, under the conditions that other abnormalities outside the scope of the research

question are not actively sought for, that the coronary artery calcium score is communicated only on request and only as neutral information, and that the information folder and the consent form are revised in accordance with the instructions from the Committee.



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