Executive summary

Health Council of the Netherlands. Population Screening Act: prevalence of gastrointestinal tract disorders studied with a video capsule. The Hague: Health Council of the Netherlands, 2015; publication no. 2015/19.

At the request of the minister of Health, Welfare and Sport the committee on population based screening of the Health Council of the Netherlands has assessed a license application for a scientific study concerning the prevalence of gastrointestinal tract disorders in the general population of 50 to 75 years of age. The applicant is the Erasmus MC in Rotterdam in the Netherlands. The investigator aims to register the prevalence of gastrointestinal tract disorders using a so-called video capsule endoscopy or camera pill. The committee has observed that for the research proposal a license is required under the Population Screening Act. It, therefore, reviewed the application in accordance with the requirements of the law.

Within the current Rotterdam study (in the Netherlands also known as ERGO) the prevalence of all kinds of disorders and abnormalities is studied. In accordance with previous recommendations by the Health Council and in view of the many important scientific publications concerning the Rotterdam study, the committee recognizes the importance of prevalence studies such as the Rotterdam study. However, the committee has not been convinced of the societal value of knowing the prevalence of all gastrointestinal tract disorders aimed for in this video capsule study.

Concerning the scientific reliability of the study proposal in the application the committee specifically reviewed the validity and the reliability of the test characteristics sensitivity and specificity of the video capsule for the different gastrointestinal tract disorders as insufficiently convincing. The sensitivity and specificity of the video capsule have insufficiently been examined. The available

evidence mainly derives from clinical study populations, and the test characteristics of the video capsule (Pillcam® Colon 2) used in the study, have not been examined outside the colon (the oesophagus, the stomach, the duodenum and the small intestine). For this reason, an accurate estimation of the frequency of missed disorders by the video capsule, is hardly possible. More important for the participants is, that the frequency the video capsule will lead to unnecessary follow-up (false positives) cannot be accurately estimated as well. Additionally no accurate estimate of the frequency of overdiagnosis and overtreatment as a consequence of the (follow-up) procedures can be made. Those disadvantages are increased because during the video capsule (as opposed to traditional endoscopy) there is no opportunity to take samples for pathology. Therefore follow-up studies will be necessary to check the prevalence data and to reach a definite diagnosis. Together with the fact that the study sample is restricted to 1,000 participants, which is determined too small for a reasonably accurate estimate of the prevalence of location specific malignancies, the committee is not convinced by the scientific reliability of the study. However, in itself it finds this insufficient ground for direct dismissal of the license application.

A study like the Rotterdam study primarily has scientific value. Secondary it can be of individual benefit for the participants, for example if clinically relevant disorders are accurately detected. Video capsule endoscopy might at first seem a simple and fast method to obtain data concerning abnormalities in the gastrointestinal tract. The procedure, however, has several disadvantages and risks. The procedure is stressful for the participant, not in the least because of the required intensive bowel preparation. Furthermore there is a small risk of retention of the video capsule, which will occasionally require surgical removal of the capsule. If abnormalities are observed these can lead to (unnecessary) anxiety concerning the clinical meaning and the clinical consequences of the findings. A further important disadvantage is that follow-up studies will be necessary to verify the clinical significance of the observed abnormalities on the images (diagnosis). A considerable proportion of the observed abnormalities will then be proven (clinically) irrelevant (false positives). Moreover overdiagnosis and overtreatment cannot be excluded. Additionally the required follow-up procedures are frequently physically and mentally stressful and can lead to complications. Furthermore the follow-up procedures will lead to costs for the participant. The number of follow-up procedures cannot be estimated accurately, but this will concern at least more than one quarter of the participants.

The committee concludes that the substantial disadvantages and risks of the study with the video capsule do not outweigh the benefits, given the

unconvincing scientific reliability and the unconvincing public health value of the research. Therefore the committee considers the benefit risk ratio of the application as negative. Consequently it recommends the minister to reject the license application, as presented by the applicant, for the study into the prevalence of gastrointestinal tract disorders with video capsule within the Rotterdam study.