

# Population Screening Act: study into hepatic steatosis and liver fibrosis in The Maastricht Study

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## Executive summary

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Health Council of the Netherlands



As part of The Maastricht Study, the Maastricht University Medical Centre intends to examine the association of hepatic steatosis and liver fibrosis with type 2 diabetes mellitus. Under the Population Screening Act (WBO), a permit is required for this research. The Committee on Population Screening of the Dutch Health Council has examined the permit application against the requirements of the WBO and advises the State Secretary of Health, Welfare and Sport (VWS) to grant the permit under the condition that the information for participants will be extended.

### **Permit application**

The applicant wishes to amend the protocol of The Maastricht Study. The Maastricht Study is an extensive population screening study into diabetes type 2, cardiovascular diseases, and other chronic disorders. In this sub-study, the applicant wishes to measure the elasticity of the liver with the Fibroscan in order to evaluate the

degree of fattening and fibrosis. The objective of the amendment is to study the relationship between hepatic steatosis and fibrosis of the liver on the one hand and diabetes type 2 on the other.

### **Review against WBO requirements**

For the committee the scientific validity of the study is sufficient. The research question is relevant and the proposed study design can provide an answer to the research question.

According to the Committee the benefit of the study outweighs the risk. The research will add to the body of available knowledge, and the measurement with the Fibroscan has a minimal impact on participants and is not associated with any complications.

However, there is a small chance that liver cirrhosis will be found, which is a risk factor for liver cancer. The participation information sheet

does not inform participants of how high the probability is that the Fibroscan will find clinically relevant hepatic steatosis, liver fibrosis, or liver cirrhosis, and what the potential consequences of such findings are for the participants. The Committee therefore finds the information provided to participants to be incomplete.

### **Advice**

The Committee advises the State Secretary of Health, Welfare and Sport (VWS) to grant the permit subject under the condition that the participation information sheet provides adequate information about the potential findings of the Fibroscan, how likely it is that these findings will occur and what the potential consequences of these findings are for the participants.



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