# Population Screening Act: a nationwide scientific study on the first-trimester anomaly scan – the IMITAS study

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# Executive summary

Health Council of the Netherlands

The regional centres for prenatal screening have jointly applied for a permit to conduct a study on an anomaly scan during the first trimester of pregnancy. The study is being conducted in cooperation with Leiden University Medical Center (LUMC) and the University Medical Center Utrecht (UMCU). At the request of the State Secretary of Health, Welfare and Sport, the Health Council of the Netherlands' Committee on Population Screening has assessed this application for a permit against the requirements of the Population Screening Act.

Like the 20-week anomaly scan, a 13-week anomaly scan can detect serious abnormalities that are usually described as being 'incompatible with life'. The pilot population study aims to determine the benefits and disadvantages of this type of early ultrasound scan.

The Committee has assessed the research proposal and concluded that it meets the legal requirements for scientific soundness. The Committee also believes that the risk-benefit ratio is favourable. The results of the study are essential for allowing a decision to be made as to whether a 13-week anomaly scan should be added to the national prenatal screening programme. The benefit for the pregnant woman is that there is more time for follow-up diagnostics and it would be expected that this gives more time for a decision about continuing the pregnancy. The disadvantages are that the ultrasound scan may lead to follow-up diagnostic testing that proves in retrospect to have been unnecessary, to stress and anxiety (or conversely to unjustified reassurance) and to further medicalisation of the pregnancy. It is important that adequate information is available about the examination and about how the 13-week anomaly scan compares to other prenatal screening option (the non-invasive prenatal test (NIPT), also offered within the context of scientific research, the combined test and the 20-week anomaly scan, which is offered as standard), so that the parents-to-be can make a voluntary and well-considered choice as to whether or not to participate.

The Committee's opinion is that the information for the participants needs to be clarified in various respects. All participants must also be informed in a separate (written) leaflet about the scientific research into 13-week anomaly scans so that it is clear that this screening is only being offered in the context of scientific research. Finally, the consent form that participants sign needs to be modified.

The Committee advises the State Secretary for Health, Welfare and Sport to grant the permit subject to the condition that the information provided for participants and the consent form are amended.

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